UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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In the Matter of:	FDA DOCKET: 00N-1571
	DATE: January 27, 2003
Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application (NADA) 140-828 (Baytril)	

Center for Veterinary Medicine's Motion to Strike Bayer Corporation's and Animal Health Institute's Written Direct Testimony and Memorandum in Support of the Center for Veterinary Medicine's Motion to Strike

The Center for Veterinary Medicine ("CVM" or "the Center") hereby moves to strike specified portions of the written direct testimony submitted by Bayer and AHI, as described in more detail in the attached Memorandum in Support of CVM's Motion to Strike Written Direct Testimony.

Respectfully submitted,

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Robert M. Spiller, Jr.

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Counsel for the Center for Veterinary Medicine

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Center for Veterinary Medicine's Memorandum in Support of its Motion to Strike the Written Direct Testimony of Bayer Corporation and the Animal Health Institute

The Center for Veterinary Medicine ("CVM" or "the Center") respectfully submits this Memorandum in Support of its Motion to Strike the Written Direct Testimony of Bayer Corporation ("Bayer") and the Animal Health Institute ("AHI").

On December 13, 2002, Bayer Corporation ('Bayer") and the Animal Health Institute ("AHI") submitted Written Direct Testimony in the above captioned administrative hearing. According to the Administrative Law Judge's April 10, 2002, scheduling order, Motions to Strike Written Direct Testimony are due on or before January 27, 2003.

21 CFR §12.94(c) provides that "[W]ritten evidence, identified as such, is admissible unless a participant objects and the presiding officer excludes it on objection of a participant or on the presiding officer's own initiative." Evidence can be excluded if it is, among other things, irrelevant, immaterial, unreliable, or repetitive. See 21 CFR §12.94((c)(1)(i).

Evidence that is not relevant to the issue for hearing should be excluded. Relevant evidence means "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Federal Rules of Evidence 401.

Evidence that is not material to the issue for hearing should be excluded. Material evidence is that which has probative weight and that is reasonably likely to help the Administrative Law Judge make a determination. (Weinstock v. United States, 231 F.2d 699 (1956) ("To be 'material' means to have probative weight, i.e., reasonably likely to influence the tribunal in making a determination required to be made. A statement may be relevant but not material.") Weinstock, at 701.

Unreliable evidence should likewise be stricken from the record. "An expert's opinion should be excluded when it is based on assumptions which are speculative and not supported by the record. *See* Eastern Auto Distrib., Inc. v. Peugeot Motors of Am., 795 F.2d 329, 337 (4th Cir. 1986)." Tyger Construction Company Inc. v. Pensacola Construction Company, 29 F.3d 137 (4th Cir. 1994).

Evidence that is repetitive should also be excluded from the evidentiary record. Federal Rules of Evidence 403 provides, "Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury, or by considerations of undue delay, waste of time, or needless presentation of cumulative evidence." (Emphasis added.)

As set out in the Notice of Hearing, (67 Fed. Reg. 7700 (February 20, 2002)), the issue at hearing is:

> "Whether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved. This issue includes:
>
> A. Whether there is a reasonable basis from which serious questions about the safety of enrofloxacin use in poultry may be inferred, such as:
>
> 1. Whether enrofloxacin use in poultry acts as a selection pressure, resulting in the emergence and dissemination of fluoroquinolone-resistant spp. In [sic] poultry?
>
> 2. Whether fluoroquinolone-resistant Campylobacter spp. in poultry are transferred to humans and whether they contribute to fluoroquinolone-resistant Campylobacter infections in humans?
>
> 3. Whether fluoroquinolone-resistant Campylobacter infections in humans have the potential to adversely affect human health?
>
> B. Whether the use of enrofloxacin under the approved conditions of use in poultry has been shown to be safe?"[1]

[1] "Enrofloxacin" and "Baytril" (Bayer's enrofloxacin product) are used interchangeably in this Motion and Supportive Memorandum.

Included in this Motion, is the request to strike any exhibits that are cited within, or for support of, any testimony that is ultimately stricken from the record.

Specific grounds for each portion of testimony subject to this Motion to Strike are set out below.

For convenience in considering similar sections of the Motion, the Center has organized this Memorandum by witnesses' subject area. The Center lists here the various testimonies subject to the Motion, by name, Exhibit Number, and page number in this Memorandum:

Witness	Exhibit	Page number in this Memorandum
Burkhart	B-1900	76
Carnevale	A-199	64
Cox	B-1901	3
DeGroot	A-200	70
Feldman	B-1902	63
Glisson	B-1903	8
Gonder	A-201	12
Haas	B-1904	6
Harris	B-1919	40
Hofacre	A-202	15
Iannini	B-1905	44
Kist	B-1906	44
Martin	B-1907	22
Newell	B-1908	21
Pasternack	B-1909	44
Patterson	B-1910	45
Prucha	A-203	57
Robach	B-1911	45
Russell	B-1912	49
Silley	B-1913	53
Smith, John A.	B-1914	18
TerHune	B-1915	20
Tompkin	A-204	60
Van den Bogaard	B-1916	56
Wages	B-1917	10
Woodruff	B-1918	32

Louis Anthony Cox, Jr.

The Center moves to strike the following designated portions of the Written Direct Testimony of Dr. Anthony Cox, Jr. for the reasons specified with each designated portion.

Page 4, Line 22 through Page 5, Line 5, Paragraph on "the risk management step of traditional risk analysis" about "the frequency and magnitude of harm change if enrofloxacin were banned?": This paragraph should be stricken because it is irrelevant to the issue for this hearing, whether Baytril is shown to be safe. If Baytril has not been shown to be safe, then it should be withdrawn, without recourse to the frequency and magnitude of the harm change.

Page 5, Lines 11-12 The sentence noting that "...tests for potential causality... (Shipley, 2000) have not been used by CVM": This sentence should be stricken as it is irrelevant and immaterial, whether CVM used all available methods or not. It is especially irrelevant that this witness (who testifies to having reviewed the CVM Risk Assessment in 1999 [Cox WDT, Page 3, at line 17]) should complain that it did not use a method said to have been published in 2000.

Page 5, Line 14 through Page 6, Line 20, paragraphs pronouncing alleged defects in the CVM analysis: These paragraphs should be stricken as unreliable, because they are wholly unsupported by proximate references to reliable citation.

Page 7, Lines 1-19 the witness's repeated main conclusions: These lines should be stricken as they are repetitions of exactly the same material as in the attachment, Page 9. This witness's attachment has un-numbered lines and bears two different page numbers on each page. References in this motion to pages in Dr. Cox's attachment will be to the bold-typed page number that is the last of three lines of bold-typed Docket and Exhibit identifying material that appears on each page.

Attachment, Page 12-14 section titled "Scoping": This section should be stricken because it is irrelevant and immaterial, as the issue for this hearing is whether Baytril has been shown to be safe, not the effects of its withdrawal (or "ban", as this witness mis-names it).

Attachment, Page 15, all but final paragraph: These paragraphs are irrelevant and misleading because they suggest that there is one type of statistical analysis: "causal analysis" that was not employed by CVM within its risk assessment and that CVM is somehow obliged to use all available types of statistical analyses, or at least that CVM must use this type of analysis.

Attachment, Page 16, first two paragraphs of "Exposure Assessment", describing "A traditional definition of exposure assessment..." and "FDA has recognized this key concept...": These paragraphs should be stricken because they are irrelevant and immaterial to the issue of this hearing, which does not involve the need for traditional definitions of exposure assessment, nor whether or not FDA has recognized concepts of those definitions. These paragraphs are also misleading because they confuse the concepts of a microbial risk assessment, such as is done to assess the risk of acquiring food-borne pathogens, with an antimicrobial resistance risk assessment, which deals not with the risk of consuming the pathogen, but with the risk of being affected by the increased resistance of pathogenic bacteria.

Attachment, Page 16, last paragraph, onto the top paragraph fragment on Page 17, complaining of CVM's focus on prevalence of fluoroquinolone-resistant *Campylobacter* instead of the microbial load of *Campylobacter* contamination on chicken: This paragraph should be stricken because it misleadingly and irrelevantly suggests that the bacterial count per unit of

chicken is the only proper measure of the risk for acquiring resistant *Campylobacter* from the chicken, and that prevalence is not an appropriate measure.

Attachment, Page 17, first full paragraph: This paragraph should be stricken because it is misleading in suggesting that the absence of significant difference in a comparison of two-chicken-consuming groups (one a group of people who may have acquired their susceptible *Campylobacter* from chicken and the other a group of people who may have acquired their resistant *Campylobacter* from chicken) somehow demonstrates that chickens are not shown to be related to acquisition of fluoroquinolone-resistant *Campylobacter*.

Attachment, Page 22, first full paragraph, portion beginning with "A more realistic assessment": This portion of the paragraph should be stricken because it is misleading for the same reason as set out next above, in that it suggests a comparison of two groups that share chicken consumption (and, therefore chicken as a risk factor) is the best way to evaluate whether chicken consumption is related to a particular outcome, and purports to be surprised to find that the comparison does not reveal a significant difference.

Attachment, Page 22 second full paragraph (all): This paragraph should be stricken as unreliable because it presumes, without citation to a reliable source, that only the "right tail" [higher levels than the graphed mean value] of a microbial load distribution matters for calculating risk. This again incorporates the unjustified assumption that microbial load, perhaps a valid measure of microbial risk in food, is the only appropriate measure of the risk of acquiring fluoroquinolone-resistant *Campylobacter* from chicken. The paragraph provides no support for the necessarily implicit contention that all values below the mean are without risk, or for the contention that microbial load is somehow superior to prevalence as an indicator of risk of such resistance.

Attachment, Page 22, last paragraph (all): This paragraph should be stricken because it is misleading and immaterial in that it attempts to substitute a new issue "risks from banning" for the actual issue for this hearing: whether Baytril is shown to be safe.

Attachment, Page 39, paragraph captioned "Incorrect chicken-attributable fraction for FQ-r CP": This paragraph should be stricken as it relies on the same invalid [for the purpose of determining the fraction of FQ-resistant *Campylobacter* cases attributable to chicken] comparison of two groups of chicken-consumers as noted below for Pages 57-60, and above for Page 17.

Attachment, sections numbered 13-17, from Pages 44 to 47, as to causal tests: This set of questions, answers and rejoinders should be stricken as they are irrelevant and misleading in that they incorporate the presumption that only a causal analysis can be used to evaluate the relationship between enrofloxacin use in chickens and human health adverse effects of fluoroquinolone-resistant *Campylobacter*.

Attachment, from "The above estimates..." on Page 57 through the last complete paragraph on Page 60: This portion of the attachment should be stricken as irrelevant and misleading because it sets up a statistical straw man, and makes much of its failure to reveal a

statistically significant attributable fraction. The straw man is the phrasing of the question implicit in the 2x2 tables arrayed by the witness at Pages 59 and 60. Those tables reveal that the witness is testing the attribution of FQ-resistant *Campylobacter* cases to chicken consumption, either in restaurants or at home, by comparing those numbers to those of FQ-sensitive *Campylobacter* cases. Because so many *Campylobacter* cases (regardless of resistance) are chicken consumers, both the FQ-sensitive and FQ-resistant cases have that same large risk factor in common, so the comparison chosen cannot discern the first desired ratio, an indication that the odds of a person with Fluoroquinolone-resistant *Campylobacter* having been exposed to chicken is more than the odds for a person with Fluoroquinolone-sensitive *Campylobacter* to have been exposed to chicken.. It is therefore not surprising (and it is immaterial) that the witness ends up with confidence intervals for his calculated odds ratios that include 1, signaling the absence of demonstration of a significant difference between his carefully-chosen similar groups. The witness's chosen comparison (and indeed the data on which he relies) does not contain a variable that distinguishes between the chicken that are contaminated with the FQ-resistant *Campylobacter*, and other chicken. This prevents the calculation from it, of the statistic of interest, the fraction of FQ-resistant human *Campylobacter* cases that are attributable to FQ-resistant *Campylobacter*-contaminated chicken.

Attachment, Pages 74-76 (all): This section of Dr. Cox's testimony should be stricken because it is irrelevant and misleading in that it attempts to substitute a non-issue, the future effects of withdrawal of Baytril, for the actual issue for this hearing, whether Baytril is currently shown to be safe. The witness's evident desire to address another issue may be well-intentioned, but it is not the issue established by the statute and the regulations and the issue set for this hearing.

Attachment, Pages 80-81, topic number 7: "Not all chicken-borne FQ-r CP [fluoroquinolone-resistant *Campylobacter*] will be eliminated by a ban on enrofloxacin.": This topic section of the testimony should be stricken as irrelevant and immaterial. Neither the Center, nor this hearing can, or purports to, eliminate <u>all</u> the fluoroquinolone-resistant *Campylobacter* that contaminates chicken, and the issue for the hearing is not the proportion of harm that will be averted, but whether Baytril is shown to be safe.

Attachment, Pages 83-87, topic number 7 "BANNING BAYTRIL WILL GREATLY INCREASE...": This topic of the testimony should be stricken as it is irrelevant to the hearing issue set for this hearing. The issue for hearing is not whether withdrawal will cause one effect or another; it is whether Baytril is shown to be safe.

Charles N. Haas

The Center moves to strike the entire written direct testimony of Charles N. Haas, Ph. D. as repetitive of the testimony of Dr. Cox.

If Dr. Haas' testimony is not stricken in its entirety, the Center moves to strike the following designated portions of the written direct testimony of Dr. Haas for the reasons specified with the designations:

Page 4, line 5, to page 5, line 21, the "National Academy of Sciences Criteria" section (all): This section of the testimony should be stricken as unreliable as not supported by a citation to hearing exhibits. The information available to the Center raises questions about the implication that the NAS set forth a meaning of risk assessment that "includes at least the following steps [the five steps listed on page 4]", but neither the Center nor the Administrative Law Judge can evaluate this testimony absent a citation to an exhibit in this record.

Page 5, line 22 to page 6, line 16, the "Office of Management and Budget / Safe Drinking Water Act" section (all): This section of the testimony should be stricken as irrelevant to the issue for this hearing, whether Baytril is shown to be safe. It appears to be an attempt at legal argument, not expert scientific testimony, and as such, should be properly left to Bayer's counsel, and should be stricken from scientific testimony.

Page 9, lines 3-5 , and the table between line 5 and line 6 (all): This testimony is irrelevant and immaterial to the issue of this hearing. Whether some food risk assessments were or were not conducted using some specific risk paradigms is irrelevant and immaterial here, and this testimony should be stricken.

Page 9, line 10 through page 10, line 2 (all): This testimony, on an unpublished study that uses a farm-to-fork risk assessment for a food risk problem should be stricken as unreliable, because it is based on a study that Dr. Haas did not conduct, and that is not available by publication for review here, nor is it cited to a hearing exhibit number. This testimony should be stricken because it is also irrelevant: it is a food risk assessment, rather than an antimicrobial resistance risk assessment.

Page 11, line 12, through page 12, line 5, the three sentences beginning "However one factor is almost surely....": This testimony should be stricken as it is unreliable speculation as signaled by its own introductory phrase.

Page 12, lines 6 through 9 (all) that begins "If, instead of the 20.5% factor...a factor of 50% was used...". This testimony should be stricken as an unreliable hypothetical without the necessary predicate facts. The ability of an expert to testify on hypothetical facts is not a license to speculate with facts not cited to the record.

Page 12, line 15, through page 13, line 9, including Figure 1 (all). This testimony should be stricken as unreliable as it is based on information "adopted from" data that was provided by personal communication to Dr. Haas over a year ago and that purports to describe trends in chicken consumption, nationwide, according to whether the chicken was "whole broilers", "parts" or "further processed", over an 18-year period. If such data were significant and reliable they would have been available by now in reliable, published, verifiable form, and Dr. Haas could have provided a citation to an numbered exhibit in this record to reflect it. The intrinsic unreliability of such information is evident in the unexplained overlap of the categories purported to be depicted, which may be overlapping categories, but are not defined to explain which line (or both) includes "parts" and "whole broilers" which are "further processed". This

would, for instance, leaves the record uncertain whether the 2000 total chicken consumption was closer to 42 pounds or 78 pounds per capita.

Page 12, lines 6-9 are separately unreliable and should be stricken as founded on a speculation that whatever proportion of chicken that were further processed "may have been processed" at a particular temperature that may have killed the bacteria. The witness does not even pretend a factual citation to justify that speculation.

Page 17, line 3, through page 20, line 19 on the criteria of the Safe Drinking Water Act (all): This section should be stricken because it is not expert scientific testimony, but a continuation of a legal argument on the applicability of certain guidelines.

Page 21, line 24, through page 22, line 9, as to whether the Center's risk assessment meets CVM guidance (all): This testimony should be stricken because it is not expert scientific testimony, but a continuation of a legal argument on the applicability of certain other guidelines.

Page 23, line 14, through page 25, line 6, as to "Microbial....[and] Chemical Benefits from the use of Fluoroquinolone in Chicken Rearing" (all): These sections should be stricken (along with the cited studies, the Russell paper and Dr. Haas' reference 10) because they are irrelevant to the issue of this hearing, which is whether Baytril is shown to be safe, not whether Baytril has other beneficial effects, such as the claim at page 24, line 6 for reduction in microbial loading in swimming water, which would seem to incorporate a recognition that runoff from poultry operations does find its way into recreational waters.

Page 25, line 8, through page 26, line 14, Dr. Haas' "Synopsis of Key Conclusions": These repetitions of segments and conclusions of Dr. Haas' testimony should be stricken as duplicative to the extent they are drawn from his testimony. To the extent they are not drawn from his testimony, or they are based on any parts of his testimony that are stricken they should be stricken as unreliable.

John R. Glisson

The Center moves to strike the entire Written Direct Testimony of Dr. Glisson as redundant and duplicative of the testimony of Drs. Gonder, Hofacre, John Smith, TerHune and Wages, which cover the same subjects, as is evident from their testimony, and from their own descriptions of their testimony as set out below:

Dr. Glisson: [Glisson Written Direct Testimony Page 2, Lines 16-19]:
"the treatment decision process for veterinarians; the appropriateness of the Enrofloxacin delivery system; the efficacy of enrofloxacin; the alternatives to enrofloxacin if the enrofloxacin NADA is withdrawn; and the comparative efficacy of these alternatives and enrofloxacin."

Dr. Wages: [Wages Written Direct Testimony Page 2, Lines 16-20]
"general turkey raising procedures/practices; the biological and rearing differences difference [sic] between chickens and turkeys; the *E. coli* and *Pasteurella multocida* disease process; the

treatment decision process for veterinarians; the enrofloxacin delivery system; the efficacy of enrofloxacin and available alternatives to enrofloxacin."

Dr. Gonder: [Gonder Written Direct Testimony, Page 3, Lines 9-14]:
"general turkey raising procedures/practices; the differences between chickens and turkeys as relate [sic] to the issues for hearing; the *E. Coli* and *Pasteurella multocida* disease process in turkeys; the turkey treatment decision process for veterinarians; the appropriateness of the enrofloxacin delivery mode as relates to turkeys; the efficacy of enrofloxacin for treating turkeys; alternatives to enrofloxacin available to the turkey veterinarian; and the comparative efficacy of alternatives to enrofloxacin."

Dr. Hofacre [Hofacre Written Direct Testimony Page 2, Lines 9-12]:
"general poultry raising procedures and practices, the nature of the *E. coli* disease process, the treatment decision process used by veterinarians, appropriateness of the delivery system to provide enrofloxacin to sick birds and the efficacy of enrofloxacin".

Dr. John Smith: [John Smith Written Direct Testimony Page 3, lines 14-17]:
"poultry raising procedures/practices; the *E. coli* disease process in broilers; treatment decision process for veterinarians; enrofloxacin delivery system; efficacy of enrofloxacin; the practical realities if Baytril is no longer available; and animal welfare issues if Baytril is no longer available."

Dr. TerHune [TerHune Written Direct Testimony, Page 3, Lines 19-20]:
"the pharmacokinectics of enrofloxacin and alternatives, as well as the appropriateness of administering enrofloxacin through drinking water systems."

In the event that Dr. Glisson's testimony is not entirely stricken, the Center moves to strike the following designated portions of his testimony for the stated reasons.

Page 5, Line 21 through Page 6, Line 7 ("Enrofloxacin is the most efficacious antibiotic....also minimizes the potential for resistance development in the target organism."): This portion of Dr. Glisson's testimony is irrelevant and immaterial to the issue of this hearing. Issues relating to comparative efficacy are not relevant to FDA approval or withdrawal decisions.

Page 6, Line 8 through Page 7, Line 3 ("In many cases...This is but a single example..."): This portion of Dr. Glisson's testimony is anecdotal, unspecified and unsupported (by citation to reliable sources) cases, and is unreliable. Further, the testimony is not material, and single, unspecified and unsupported cases are even less material. To the extent that the testimony might seek to establish the efficacy of enrofloxacin, at the time of approval; that is established by the Center's approval of the NADA, without the need of testimony.

Page 7, Lines 5-10 ("In general....the only available drugs <u>specifically approved</u> to treat E. coli infections in chickens older than three days of age and E. coli and Pasteurella multocida infections in turkeys older than three days of age are:....") [emphasis supplied]: The Center moves to strike this testimony on the ground that it is irrelevant and immaterial. First, whether alternative drugs exist is irrelevant and immaterial to whether Baytril is shown to be safe.

Second, it does not matter what the specifically approved drugs are, because some drugs are permitted for use beyond their labeled indications. Therefore, this portion of Dr. Glisson's testimony should be stricken from the evidentiary record of this hearing.

Page 7, Lines 11-13 and Figure 1 on Page 8: These portions of Dr. Glisson's testimony are unreliable. Both are without visible citation to a reliable source, and the testimony identified on Page 7 is based upon Figure 1, which in turn, is without a citation to a reliable source. Therefore, these portions of Dr. Glisson's testimony should be stricken from the evidentiary record of this hearing.

Page 8, Line 9 through Page 9, Line 2 (all): This testimony concerning sulfa drugs is irrelevant and immaterial to the issue in this hearing: whether Baytril is shown to be safe; and should be stricken from the evidentiary record of this hearing.

Page 9, Line 3 through Page 11, Line 2 (all): The comparative efficacy of enrofloxacin is not at issue in this hearing. Therefore, this portion of Dr. Glisson's testimony is irrelevant and immaterial to whether Baytril is shown to be safe, and should be stricken from the evidentiary record of this hearing.

Page 11, Lines 13 – 16 ("this disease causes...broiler chickens.") This portion of Dr. Glisson's testimony is irrelevant to the issue for hearing. Ramifications of E. coli infections, and economic impact to affected farmers and companies, are not relevant to the issue of whether Baytril is safe. Therefore, this portion of Dr. Glisson's testimony should be stricken from the evidentiary record of this hearing.

Page 11, Lines 17-18 ("At this time, enrofloxacin is ...serious residue risks or both."): This portion of Dr. Glisson's testimony is unreliable and unsupported by any citation, and it is contrary to fact, as the Administrative Law Judge may take judicial notice of, from the regulations setting out approved dosage forms and conditions of use (e.g. 21 CFR §520.2345d(d)(3)(ii) and 21 CFR §520.2158a). Further, this testimony is irrelevant to the issue for the hearing. The efficacy of Baytril and residues from alternative drugs are not related to the safety of Baytril. Therefore, this portion of Dr. Glisson's testimony should be stricken from the record as unreliable and irrelevant.

Dennis Wages

The Center moves to strike the entire Written Direct Testimony of Dr. Wages as redundant and duplicative of the testimony of Drs. Glisson, Gonder, Hofacre, John Smith, and TerHune, which cover the same subjects, as is evident from their testimony, and from their own descriptions of their testimony as set out above (these descriptions are quoted above in the specification of the Motion to Strike as to Dr. Glisson's testimony).

In the event that Dr. Wages' testimony is not entirely stricken, the Center moves to strike the following designated portions of his testimony for the stated reasons.

Page 7, Lines 10-14 ("Acidifying litter treatment products may be used between house placements in the grow-out houses to reduce residual bacterial contamination and to control ammonia in the litter. Acidification treatment is bactericidal as bacteria do not survive acidic environments. Such treatment is known to control *Campylobacter*. (B-1850)."): This portion of the testimony is unreliable because actual field use of the acidification described in the cited work is not reflected in the cited work, and no statistic is provided for what percentage of houses use this procedure. Additionally the "may be used language" signals that the allegation is speculative, and therefore unreliable. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing.

Page 8, Lines 14-15 ("Because fowl cholera occurs more frequently in older turkeys, the financial hardship of loss due to an outbreak can be very substantial."): The financial impact of an outbreak is irrelevant to the issue for hearing and, therefore, this portion of Dr. Wages testimony should be stricken from the evidentiary record.

Page 11, Lines 13-15 ("While it is true that enrofloxacin is used infrequently, in less than 4% of all turkeys produced nationwide, when outbreaks occur enrofloxacin is necessary to save a 'region' of turkey production."): This portion of Dr. Wages' testimony is unreliable in that it is not supported by citation to a reliable source; and incorporates an unsupported one-sided "in less than" statistic. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing.

Page 12, Lines 2-4 ("Both these conditions increase intestinal fragility and increase the difficulty of removing intestines intact during processing. Interrupted eating leads to uneven loading in the intestinal tract, making mechanical or manual evisceration at normal line speeds more difficult."): This portion of Dr. Wage's testimony is unreliable in that it is not supported by citation to a reliable source; and incorporates an assumption not justified in the testimony, that the line speed must remain static, and that the process must accommodate mechanical evisceration. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing.

Page 12, Lines 6-8: ("Broilers and turkeys that 'go off feed' early are more likely to be populated with *Campylobacter* and *Salmonella*."): This portion of the testimony is unreliable in that it is not supported by a citation to a reliable source. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing.

Page 12, Lines 9-13 The potential for thinning of the intestinal wall is not reliable because it only goes to support a speculative argument about increased pathogens at the slaughter house. This argument assumes that no other drug will be effective and that other changes cannot be made in animal husbandry or in processing to avoid the processing of sick birds. These assumptions are so speculative as to be unreliable. It is also unreliable in that it is not supported by a citation to a reliable source. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing.

Page 18, Lines 19-20 ("Enrofloxacin is highly effective. The dose is designed to minimize resistance in the target pathogen."): This portion of Dr. Wages' testimony should be

stricken because it is irrelevant and immaterial to the issue of the safety of Baytril. Efficacy is not an issue for this hearing. Further, it is immaterial since the testimony provides that the dose is designed to minimize resistance in the target pathogen, which is not Campylobacter. The fact that the dose is or is not designed to minimize resistance in a different pathogen is not material to the issue at hearing. Additionally, this sentence should be stricken because it is unsupported by citation to a reliable source.

Page 18, Line 21: Dr. Wages vague recollection of the number of clinical successes he has seen is not relevant to the issue for this hearing, and, if relevant, would be immaterial. Therefore, this portion of Dr. Wages testimony should be stricken from the evidentiary record of this hearing.

Page 19, Line 13 ("In reality, therefore, there are no alternatives to enrofloxacin."): The existence or non-existence of treatments other than Baytril is irrelevant and immaterial to the question of whether Baytril is safe. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing. Further, because this portion of Dr. Wages' testimony is unsupported by citation to a reliable source, it is unreliable and should be stricken.

Page 20, Lines 16-21 (all): This paragraph is unsupported by citation to a reliable source. Therefore, this portion of Dr. Wages' testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 21 (all): These conclusions, without separate support exceed the supported statements within the body of the testimony, and are therefore unreliable. Further, the testimony of Page 21, Lines 1-8 and 10-11 are unrelated to the issue for hearing and should be stricken as irrelevant. Further, this entire portion of Dr. Wages' testimony is repetitive and should be stricken from the record.

Eric Gonder

The Center moves to strike Dr. Gonder's entire Written Direct Testimony as redundant and duplicative of the testimony of Drs. Glisson, Hofacre, John Smith, TerHune and Wages, which cover the same subjects, as is evident from their testimony, and from their own descriptions of their testimony as set out above (these descriptions are quoted above in the specification of the Motion to Strike as to Dr. Glisson's testimony).

In the event that Dr. Gonder's testimony is not entirely stricken, the Center moves to strike the following designated portions of his testimony for the stated reasons.

Page 4, Lines 2-4 ("Eggs may be shipped from North Carolina to California, day-old poults may be shipped from North Carolina to Minnesota, and market birds may be shipped 200-250 miles.") These "may be" statements are unreliable speculation by their own terms, and should be stricken as unreliable.

Page 5, Lines 16-18 ("If it costs $0.07 per head to move birds from the brooder to a finishing house, for a 42 pound tom that is only $0.016 per pound but for a 14 pound hen is a much harder-to-recover $0.05 per pound.") This testimony should be stricken as unreliable, because it begins with an unsupported speculation, and compounds that defect by two successive arithmetic errors, which result in both the tom and hen cost figures being multiplied ten times the correctly multiplied value. Additionally, financial costs are not relevant or material to the issue for hearing. Therefore, this portion of Dr. Gonder's testimony should be stricken as unreliable, irrelevant, and immaterial.

Page 12, Lines 2-3 ("Scalding temperatures in some turkey plants are now a little higher – 58 to 62° C (137-143° F) due to the larger size of the turkey being processed now.") This factual allegation should be stricken as unreliable because it is unsupported by any citation to a reliable source, in marked contrast to the two preceding sentences.

Page 13, Lines 10 through Page 14, Line 7, concerning "...a study of 4-week-old turkeys with faculty at North Carolina State University...". The study (or studies), if published, is not cited, nor is its data made available. Testimony about, and based on, this study should be stricken as demonstrably irrelevant, according to the witness's own testimony at Page 4, Lines 10-11, where he testifies that the relevant marketing age for turkeys is from 10-24 weeks. The unreliability of this testimony without citation is enhanced by the unquantified phrase: "little Campylobacter could be recovered from 17 [of 29 farms]".

Page 14, Lines 15-19 ("The turkey...the intestinal microflora should be much more stable....This maturity should result in an intestinal microflora....which should reduce the number of enteric pathogens...") These sentences should be stricken as unreliable: they are self-identified as a concatenation of supposition, speculation upon speculation. Even if the statement were a fair summary of the cited work, it would be but cited speculation, and still unreliable.

Page 15, Lines 9-11 ("Consumer exposure to *Campylobacter jejuni* from our products should be substantially lower...") This sentence should be stricken as unreliable speculation. Further, it is not material that exposure to Campylobacter jejuni is lower than 10-20 years ago.

Page 15, Lines 12 –23 (all): This portion of Dr. Gonder's testimony is irrelevant and immaterial to the issue for hearing. Cost information is not related to whether Baytril is shown to be safe, nor will it assist the Administrative Law Judge in making a determination on the issue for this hearing. Therefore, this portion of Dr. Gonder's testimony should be stricken from the evidentiary record of this hearing.

Page 17, Lines 7-9 ("This tends to make the infections quite unpredictable in terms of morbidity and mortality, or the management steps necessary to limit their severity.") This fragment should be stricken as unintelligible, and therefore unreliable.

Page 18, Line 9, through Page 20, Line 3: The entire section captioned "Outbreaks are regional and cyclical". This section is irrelevant and immaterial to the issue of this hearing, whether Baytril is shown to be safe. Even if it were true that outbreaks of Campylobacter in poultry were regional and cyclical, that would not be material, because the safety issue is not dependant on national-sized outbreaks, nor on steady (as opposed to cyclical) outbreaks. Further, to the extent that none of this testimony refers to Campylobacter or other enteric bacteria, it is irrelevant and immaterial and should be stricken from the evidentiary record of this hearing.

Page 23, Lines 13-16 (all): This technical assumption is unreliable, as it is unsupported by any citation to a reliable source, and fails to identify a basis, even within this testimony, for the conclusion.

Page 23, Lines 17-21 (all): These sentences should be stricken as unsupported by any citation to a reliable source. Further, this testimony assumes that no other drug therapy is available and that no husbandry or other industry change can reduce the incidence of fecal contamination. Therefore, this portion of Dr. Gonder's testimony should be stricken as unreliable.

Page 30, Line 4 through Page 31, Line 4 ("Fluoroquinolones are the sole antibiotic effective against..."): This portion of Dr. Gonder's testimony should be stricken because it is irrelevant to the issue of this hearing. Efficacy, and comparative efficacy, of Baytril is not relevant to the issue of whether Baytril is shown to be safe.

Page 31, Line 4-8 ("Barring substantive change in the regulatory and research climate at CVM and the pharmaceutical industry, I anticipate no new therapies forthcoming...June of 2000"): This portion of Dr. Gonder's testimony should be stricken as unreliable speculation. The witness's anticipation of therapies in response to the future climate is immaterial, as well. Further, the availability and/or use of competitive exclusion products are not relevant or material to the issue of whether Baytril is shown to be safe.

Page 31, Lines 8-11. The sentence that notes that an unidentified "product that appeared to have promise...was withdrawn...when another [unidentified] product ...was approved". This sentence should be stricken because it is unreliable, in part because it lacks citation to a reliable source, and because it intentionally conceals the subjects of which it complains, preventing verification.

Page 31, Line 12 through Page 32, Line 1 ("Are there any...can be developed."): This portion of Dr. Gonder's testimony is irrelevant and immaterial. The availability of other therapies is not related to whether Baytril has been shown to be safe and will not assist the Administrative Law Judge in making a determination in this matter. Therefore, this portion of Dr. Gonder's testimony should be stricken from the record.

Page 32, Lines 1-4 ("If you assume that our improved local results at Goldsboro Milling Company between 1996 and 2000 are due to management...."): This sentence should be stricken because it is unreliable, inviting the Administrative Law Judge to join in

an assumption unsupported by citation to reliable source, and because it is wholly irrelevant to the issue for this hearing.

Page 32, Lines 10-16 ("If you believe...then you have to believe..."): This portion of Dr. Gonder's testimony should be stricken because it is unreliable and because it seeks to usurp the role of the Administrative Law Judge by requiring one finding to follow another.

Page 32, Line 17 through all of Page 33: These paragraphs should be stricken because they are unreliable in that they recite (without providing source data that can be checked or audited) differences between "our 1996 results" and the results for the 12 months ending in November, 2000; and attribute the positive changes entirely to fluoroquinolones. The testimony does not even allege (and would not be believable if it did) that the use of fluoroquinolones was the only variable that changed between 1996 and 2000, and it does not even pretend to explain why it chose one calendar year of all the pre-fluoroquinolone-use years to compare with one particular 12-period (not a calendar year) from two other years, about four years apart. This unreliable speculative assumption is followed by speculation of the imagined losses avoided: "Not feeding the turkeys that would have died...saved us some...." [Page 32, at Line 21]. Such speculation has no place among the evidence for this hearing.

Page 34, Line 1 through Page 35, Line 18 (all): The comparative efficacy of available therapy and residue limit issues are not relevant or material to the issue of whether Baytril has been shown to be safe. Therefore, this portion of Dr. Gonder's testimony should be stricken from the evidentiary record of this hearing.

Page 36, Lines 3-5 ("Then enrofloxacin will be needed in that region because an outbreak can devastate a region's production."): This sentence should be stricken because it is irrelevant. The need for the drug and the (presumably financial) devastation from an outbreak are not relevant to whether the drug is shown to be safe.

Page 36, Lines 5-6 ("Baytril is the only efficacious drug....in turkeys"): This sentence should be stricken because it is irrelevant: the effectiveness of Baytril is not an issue for this hearing.

Chuck Hofacre

The Center moves to strike the entire Written Direct Testimony of Dr. Hofacre as redundant and duplicative of the testimony of Drs. Glisson, Gonder, John Smith, TerHune and Wages, which cover the same subjects, as is evident from their testimony, and from their own descriptions of their testimony as set out above (these descriptions are quoted above in the specification of the Motion to Strike as to Dr. Glisson's testimony).

In the event that Dr. Hofacre's testimony is not entirely stricken, the Center moves to strike the following designated portions of his testimony for the stated reasons.

Page 7, Lines 19-20: ("Escherichia coli [E. coli] is the leading disease that causes economic loss to the poultry industry throughout the world (B-1412)." The sentence is irrelevant. Financial costs have nothing to do with the issue at hearing. Therefore, this sentence should be stricken from the evidentiary record of this hearing.

Page 8, Lines 2-13 All sentences from the one that begins on Line 2, through the one that ends on Line 13 should be stricken because they are unreliable, as based on citations that are not exhibits on this record, nor are they even translated to full cites and listed as a part of Dr. Hofacre's testimony.

Page 8, Lines 12-19 (all): The pathology of systemic E. coli infections is not relevant or material to the issue for hearing. Therefore, this portion of Dr. Hofacre's testimony should be stricken for the evidentiary record of this hearing.

Page 9, Lines 15-21: With respect to the part of this testimony about birds that suffer from E. coli infections having higher fecal contamination, this testimony is speculative and therefore unreliable. It assumes that there are no other therapy options or changes in husbandry/slaughter practice. Therefore, this portion of Dr. Hofacre's testimony should be stricken.

Page 9, Line 10 through Page 10 Line 11 (all): The testimony concerning financial cost to the industry is not relevant or material to the issue for hearing and, therefore, this portion of Dr. Hofacre's testimony should be stricken from the evidentiary record.

Page 12, Lines 10-12: ("It is known by the poultry veterinarians for those poultry companies affected that the level of mortality and condemnation would have been much greater had they not had Baytril to treat many of the affected flocks.") This portion of testimony should be stricken because it is irrelevant to the issue for this hearing (which is safety, not efficacy) and because it is a unreliable speculation about what is known by some other persons about something that "would have been".

Page 12, Line 12 through Page 13, Line 2: ("Poultry veterinarians know ... in broiler chickens.") These sentences should be stricken as unreliable in that they begin with unattributed knowledge of unknown veterinarians and end with the anticipation of the future need for Baytril based on speculation and because the need for Baytril is not relevant to the issue for hearing.

Page 13, Lines 6-15: ("When a new virus enters the city and no one has antibodies to fight..." and ending with "...they may die.") This portion of testimony should be stricken as irrelevant as it purports to describe a human viral outbreak and this hearing is on the issue of the safety of a veterinary drug to treat poultry for a bacterial (not a viral) disease.

Page 14, Lines 10-13: ("Also, experienced poultry veterinarians know that ...."). This portion of the testimony should be stricken because its own terms reveal that it is unreliable speculation about what other experienced veterinarians know, and is additionally unreliable because it goes on to speculate what these veterinarians know, without any citation to a reliable

source for the proposition that it is speculated they know. Further, it is unreliable because it assumes no change in husbandry or industry practice can prevent contamination.

Page 14, Lines 14-19: ("E. coli is a very expensive disease ... infected birds.") Financial cost to the industry is not relevant or material to the issue for hearing. Therefore, this portion of the testimony should be stricken from the record.

Page 15, Lines 18-20 and Page 17, Figure 4. This figure and the testimony that relies upon it should be stricken as unreliable and misleading, because the figure has been constructed in such a way that the legend box conceals the quantifying bars that purport to reflect measures of the resistance of nalidixic acid and sarafloxacin. This misleading feature of this figure is demonstrably avoidable as the evidently similar (but likewise not attributed) Figure 1 in the Written Direct Testimony of Dr. Glisson, at Page 8. In Dr. Glisson's testimony, the data are not obscured by the legend box. Fortunately, the Figure and related text is irrelevant as well (and therefore should be stricken) because it describes the resistance developed to a host of drugs by a different organism than the primary one (*Campylobacter*) that raises the safety issue with Baytril that is the subject of this hearing.

Page 17, Lines 12-15 (all): Financial issues are not relevant or material to the safety of Baytril. Further, the testimony should be stricken because it is patently unreliable and immaterial that one (unnamed) person should have confided in Dr. Hofacre that one broiler company estimates anything.

Page 24, Line 1 through Page 27 Line 4: Availability of treatment alternatives is not relevant or material to whether Baytril is safe and, therefore, this portion of Dr. Hofacre's testimony should be stricken from the record. Further, Page 24, Lines 2-3 should be stricken as unreliable as directly contradicted by this witness's own testimony [his Table 1 on Page 16 lists 12 such drugs, and the bottom of Page 24 lists 9 of these 12 drugs that are available for water therapy]. And, on Page 25, Line 18, the words "very safe" should be stricken as they are unreliable without citation to a reliable source.

Page 28, Lines 6-11 (all): Availability of treatment alternatives is irrelevant to the issue for hearing and should be stricken from the record of this hearing.

Page 28, Lines 12-18: The sentence that purports to characterize another witness's background of poultry husbandry should be stricken as an unreliable characterization of another witness's credibility. Further, weighing the relative credibility of each witness is the Administrative Law Judge's prerogative.

Page 28, Lines 15-16: ("I cannot imagine any change in poultry housing conditions that would make all health problems go away so that we would never have to use antibiotics again."). This portion of the testimony should be stricken because the ability of the witness to imagine any particular thing is irrelevant and immaterial to the issue for this hearing, and because it misleadingly suggests that CVM or this hearing is directed to a goal of making all health problems go away.

Page 29, Line 19 through Page 30, Line 3: This testimony should be stricken as unreliable if its only supporting citation, Figure 4 is stricken as moved above [regarding Page 17]. This testimony is immaterial even if the misleading figure 4 were in evidence, as it is not attributed to any verifiable publication, and (taking its caption to be true) does not purport to cover samples except at one laboratory. The embedded allegation that only one drug is available is additionally unreliable in that it is contradicted by this witness's own testimony at Pages 16 and 24.

Page 30, Lines 4-10 (all): This portion of the testimony should be stricken because it is irrelevant and immaterial. Further, Page 30 Lines 8-10 ("...we should not experience a significant level of resistance in the poultry *E. coli* isolates to enrofloxacin.") should be stricken as irrelevant to the issue of whether enrofloxacin contributes to the level of resistance of *Campylobacter* isolates in poultry. It additionally should be stricken because it is unreliable speculation to opine on what we "should not experience".

Page 30, Lines 12-13: "Systemic Escherichia coli...bacterial disease.") Financial issues are not relevant or material to the safety of Baytril. Therefore, this portion of Dr. Hofacre's testimony should be stricken from the evidentiary record of this hearing.

Page 30, Lines 19-20 ("Baytril is the ...E. coli") and Page 31, Lines 3-4 ("There is really no...in poultry."): These conclusory statements about the available effective treatments should be stricken because they are irrelevant to the sole issue of the safety of Baytril.

John A. Smith

The Center moves to strike the entire Written Direct Testimony of Dr. John A. Smith as redundant and duplicative of the testimony of Drs. Glisson, Gonder, Hofacre, TerHune and Wages testimony, which cover the same subjects, as is evident from their testimony, and from their own descriptions of their testimony, as set out above (these descriptions are quoted above in the specification of the Motion to Strike as to Dr. Glisson's testimony):

References in this section to "Dr. Smith" are to Dr. John A. Smith, and not to Dr. Kirk Smith.

If the testimony of Dr. Smith is not stricken entirely, the Center moves to strike the following designated sections, for the reason specified with the designation.

Page 17, lines 3-6, the two sentences on the reuse of litter used on the chicken-house floor: These sentences should be stricken as unreliable, as they are without any citation to reliable sources on this record.

Page 17 lines 13-15 (all): These sentences about unspecified litter treatments becoming popular, and the claim that they "may decrease" some problems, aiding bird health, are unreliable for lack of a citation to a reliable source on this record and speculative in that they do not even

allege how widespread the claimed usage is, or which species are said to be affected, and how they affect bird health.

Page 19, line 4 through page 20, line 22, (all) This section entitled "Outbreaks are Regional and Cyclical", like the section of the same name in Dr. Gonder's testimony, is irrelevant and immaterial to the issue of this hearing, whether Baytril is shown to be safe. Even if it were true that outbreaks of *Campylobacter* in poultry were regional and cyclical, that would not be material, because the safety issue is not dependant on national-sized outbreaks, nor on steady (as opposed to cyclical) outbreaks. Further, to the extent that none of this testimony refers to *Campylobacter* or other enteric bacteria, it is irrelevant and immaterial and should be stricken from the evidentiary record of this hearing.

Page 23, line 14-15 and lines 19, three sentences that read: "Lack of normal nutrient throughput causes their intestines to become thin and fragile." and "Both these conditions [diarrhea and interrupted eating patterns] increase intestinal fragility and increase the difficulty of removing intestines intact at processing. Interrupted eating leads to uneven loading in the intestinal tract, making mechanical or manual evisceration at speed more difficult.": These sentences should be stricken as unreliable because they are unsupported by any citation to the witness's own work, or to any reliable citation to an exhibit in this record.

Page 23, line 23, to page 24, line 2: "Broilers and turkeys that "go off feed" early are more likely to be populated with *Campylobacter* and *Salmonella*.

and

Page 23, lines 3-8 (all): These passages should be stricken as unreliable because they are unsupported by any citation to the witness's own work, or to any reliable citation to an exhibit in this record.

Page 25, lines 16-18: These two sentences, on the expense and relative efficacy of enrofloxacin, should be stricken because they are irrelevant and immaterial to the issue for this hearing, whether Baytril is shown to be safe.

Page 28, lines 6-8 (all): This sentence, stating (without citation) the basis of Bayer's selection of the prescribed dose range for Baytril should be stricken as irrelevant and immaterial to the hearing issue, and unreliable as well, absent any citation or any mention in Dr. Smith's testimony about the basis of his knowledge of the bases on which Bayer selected this range.

Page 28, lines 15-17. This glowing testimonial to Baytril should be stricken as irrelevant, immaterial, and unreliable as it is without citation to any exhibit in this record, and uses a standard so flexible that is as reliable as a marketing phrase: "...in the manner expected of an effective antimicrobial."

Page 28, line 1, through page 31, line 20, sections titled "Efficacy of Enrofloxacin and Alternatives", "Practical realities if Baytril is no longer available" and "Animal Welfare Issues If Baytril Is No Longer Available" : These sections, by their titles and their content, are entirely

irrelevant and immaterial to the issue for this hearing; if Baytril is not shown to be safe, none of this testimony will make it safe, or justify its continuation in approved status. If Baytril is shown to be safe, none of this testimony is necessary to sustain it.

Page 31, line 21 through page 32, line 11, Conclusion (all): All of the conclusions should be stricken as irrelevant and immaterial to the issue for this hearing.

Terry TerHune

The Center moves to strike the entire Written Direct Testimony of Dr. TerHune as redundant and duplicative of the testimony of Drs. Glisson, Gonder, Hofacre, John Smith, and Wages, which cover the same subjects, as is evident from their testimony, and from their own descriptions of their testimony, as set out in their respective testimonies and quoted at the beginning of this Memorandum's section on Dr. Glisson's testimony.

If the testimony of Dr. TerHune is not stricken entirely, the Center moves to strike the following designated sections, for the reason specified with the designation:

Page 4, lines 10-12, "CVM apparently assumes..... This general assumption is incorrect.": These sentences should be stricken because they are irrelevant, immaterial, and unreliable. CVM's assumptions are not evidence, Dr. TerHune's perception of them is not material, and it is unreliable to rely on his apprehension of someone else's assumption without a citation to whatever it is that made him think that CVM assumes something.

Page 5, lines 10-14, "CVM states that "the practice of treating the whole herd or flock is more likely to result in resistant pathogens than individual treatment due to the inability to control each animal's dose... [no cite given for the quote] But, the safety and efficacy data contradict this. Safety and efficacy tests demonstrated that diseased birds drank the medicated water in sufficient quantities to treat disease". [footnote omitted]: These sentences should be stricken as unreliable for two reasons: First, because they purport to be based upon a quote, but the quotation is not cited, so neither the Center nor the Administrative Law Judge can confirm or refute the quotation's accuracy. Second, because it would be misleading if the reader accepted the erroneous failure to distinguish between the likelihood of creating resistant pathogens such as *Campylobacter* which live in the gut of the dosed animal; and efficacy against the target organism, such as *Pasteurella multocida*. The testimony would mislead a reader into assuming that if the Baytril kills the target organism, there would be no resulting resistant pathogens from gut bacteria that did not receive a lethal dose of the Baytril.

Page 6, lines 15 through page 7, line 10, concerning the testimony of Dr. McDermott (Exhibit G-1465): This testimony should be stricken as unreliable, as it misleadingly dismisses the concern for resistance incurred in *Campylobacter*, because "*Campylobacter* is not a poultry pathogen" [B-1915, page 7, lines 9-10]. But the same testimony cited by Dr. TerHune, the testimony of Dr. McDermott, explicitly recognizes "fluoroquinolone-resistant foodborne *Campylobacter* infections in humans". [G-1465, page 7, lines 44-45]. That the witnesses disagree, of course, does not itself make Dr. TerHune's testimony misleading. But his decision

to not acknowledge that the testimony he read explained how the resulting resistance in *Campylobacter* affected the safety of humans is misleading in a hearing where the issue is whether Baytril has been shown to be safe. Because this testimony is misleading, it should be stricken.

Diane G. Newell

The Center moves to strike the following designated parts of the written direct testimony of Dr. Diane G. Newell. Dr. Newell's testimony bears two sets of page numbers, each with breaks in the numbering series, and the numbers diverge, beginning at page 40. In this motion, the page numbers used will be those in the three-line Docket numbering label, usually on the lower right corner of each page, unless a separate page identification is signaled.

Page 17, lines 1-6, "Gaunt and Piddock 1993/4, before enrofloxacin was licensed for use in the UK, undertook a small survey of retail domestic and foreign produced poultry products. Ciprofloxacin-resistant campylobacters were found in one of 64 UK-produced chickens (Piddock, 1995). This indicates that resistant campylobacter can be acquired by broiler flocks, other than by treatment.": These sentences should be stricken as unreliable because they are contradicted by the witness's own testimony [Newell WDT, page 40, lines 9-10]: "fluoroquinolones were first licensed for use in cattle, pigs and poultry in Great Britain in 1993". See also, Revised Joint Stipulation # 65, filed December 24, 2002 (stipulating that 1993 was the year of first registration for enrofloxacin in the United Kingdom).

Page 18, lines 8-10, "The reported emergence of fluoroquinolone resistance in poultry campylobacters following licensing of use of enrofloxacin is questionable as data on resistance prior to this time is not available.": This sentence should be stricken, as it is unreliable, being contradicted by this witness's own testimony on the previous page, at lines 1-4.

Page 21, lines 3-5, "For example in England and Wales the prevalence of domestically-acquired human salmonellosis, from 1992 to 2000, was stable and then in 1998 bagan [sic] to decline dramatically...." This sentence should be stricken as the prevalence of salmonellosis in England and Wales is irrelevant to the issue for this hearing. This sentence should also be stricken as unreliable because it is fatally self-contradictory in stating that prevalence was stable from 1992 to 2000 and dramatically declined, beginning in 1998.

Page 23, lines 8-10, "It is difficult to ascertain why this assumption exists or even why such entrenched views persists [sic] even in the face of clearly contradictory evidence (Tam et al., 2002; Allos, 2002)." This sentence should be stricken because it is unreliable in that what it purports to be two references, are (according to the witness's reference list at pages 52 and 78), the same document. The form of the citation does not allow the Center or the Administrative Law Judge to determine which (if any) of Bayer's exhibits these are, because the cite is not provided to an exhibit number on this record. These cites are not, therefore "clearly contradictory evidence" of anything on this record, and do not provide support for the statement.

Page 23, lines 21-22, "However, analysis of the available data indicates that this interpretation is misleading (TESTIMONY OF ROGER) [sic]." This sentence should be stricken as unreliable, as it is evidently dependant on the testimony of "Roger", but the testimony is not cited. Without its sole claim of support, the sentence is plainly unreliable. If the Administrative Law Judge were to speculate that the reference was intended to be to the testimony of Dr. Roger Feldman, at page 40, lines 5-16, where a similar allegation is made, then this testimony should be stricken as repetition. (The Feldman testimony segment is also the subject to the Center's Motion to Strike, because it too is repetition of Cox testimony).

Page 23, line 22 through page 24, line 10, Testimony about an Icelandic study, referenced to no Bayer exhibit number and referenced only to "Stern *et al.*, 2002". The witness's reference list, however, reveals that the Stern work is not yet published and recites that it is "in press". These sentences are therefore unreliable, and should be stricken.

Page 24, lines 17-19. "Thus these naturally-occurring epidemiological experiments give no clear indications that poultry is a major source of human campylobacteriosis.": This sentence is explicitly founded on the preceding examples, including the Belgian and Icelandic incidents, as to which the supporting statements were unreliable, as set out immediately above, so this sentence, also, is unreliable and should be stricken.

Page 25, lines 7-8, "The reasons for this are unclear but biased data collection is likely." This sentence is patently unreliable within scientific testimony, signaling as it does, that the conclusion "biased data collection is likely" was made without the benefit of clear reasons. This sentence should be stricken.

Page 35, line 22 through page 36, line 4, the entire bulleted paragraph to the effect that some poultry strains [of bacteria] do not cause illness in humans: This paragraph should be stricken as irrelevant and immaterial because the fact that not all bacteria on poultry are pathogenic to humans does not relate to, nor tend to show the safety of, Baytril.

Page 41, lines 16-22, "Moreover, it seems that....being actively sought": These sentences, concerning the risk of infection of poultry meat in Great Britain with ciprofloxacin-resistant organisms, and the greater controls there, compared to other countries, should be stricken, as irrelevant and immaterial to the issue for this hearing on the United States use, of whether Baytril has been shown to be safe.

Page 44, line 20, through page 46, line 16: These paragraphs concerning virulence factors for *Campylobacter*, and the various toxic mechanisms of *Campylobacter* are irrelevant and immaterial to the issue for this hearing, whether Baytril has been shown to be safe. These paragraphs should be stricken as irrelevant and immaterial.

G. Thomas Martin, Jr.

CVM moves to strike the Written Direct Testimony of Mr. Martin in its entirety because his testimony is irrelevant to the issue of hearing. The ultimate issue of the hearing as set out in

the Notice of Hearing is "[w]hether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved." (67 Fed. Reg. 7700 (February 20, 2002)). Mr. Martin presents testimony on the economic impact of the withdrawal of Baytril for use in poultry flocks (Martin WDT, Page 3, Lines 2-4). Nothing in the Federal Food Drug and Cosmetic Act (FDCA) requires, or even permits, an evaluation of the economic cost of withdrawing a new animal drug from market.

As argued in CVM's April 22, 2002 Response to Bayer's Motion to Reformulate Issues of the Hearing (Bayer's Motion denied by Order dated April 26, 2002), CVM believes that without explicit statutory authorization, economic costs may not be considered in determining the safety of a drug. This includes both the costs associated with lost revenue from poultry producers, drug manufacturers, and consumers, as well as environmental costs and other socio-economic costs. The Supreme Court has twice addressed this issue, first in American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490 (1981) and more recently in Whitman v. American Trucking Association, 531 U.S. 457 (2001). American Textile Manufacturers Institute, Inc. v. Donovan, 452 U.S. 490 (1981), involved a challenge to the cotton dust standard promulgated by the Occupational Safety and Health Administration (OSHA) under Section 6(b) of the Occupational Safety and Health Act of 1970, 29 U.S.C. §655(b). That section provided that the Secretary must set the standard "which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health..." The Petitioners argued that the term "feasible" in the Act included a requirement to conduct a cost/benefit analysis. The Supreme Court rejected this position, holding that, "When Congress has intended that an agency engage in cost-benefit analysis, it has clearly indicated such intent on the face of the statute." American Textile, 452 U.S. at 509. There, even when Congress spoke to a standard that was feasible (in every respect, including technologically and economically), the Court refused to interpret that provision as requiring OSHA to weigh the costs of the standard versus the benefits accrued by the standard.

In Whitman v. American Trucking Association, 531 U.S. 457 (2001), the Supreme Court held that the Clean Air Act bars EPA from considering implementation costs when setting appropriate National Ambient Air Quality Standards (NAAQS) at a level to protect public health. The Court held that consideration of implementation costs

> is *both* so indirectly related to public health *and* so full of potential for canceling the conclusions drawn from direct health effects that it would have been expressly mentioned in §§108 and 109 had Congress meant it to be considered. Yet while those provisions describe in detail how the health effects of pollutants in the ambient air are to be calculated and given effect, See §108(a)(2), they say not a word about costs.

American Trucking Association, 531 U.S. at 469. [Emphasis in the original.] This holding applies equally to a drug safety determination under the FDCA because consideration of costs in the drug safety determination is both so indirectly related to public health and so full of the potential to cancel the conclusions drawn from public health benefits. The FDCA does not on its face require a consideration of costs (or economic benefits) in evaluating the safety of a

drug. Under American Textile and American Trucking Association, it would be impermissible to consider such costs. [2]

Additionally, CVM moves to strike Mr. Martin's testimony in its entirety because it is so speculative as to be unreliable. The testimony presented makes assumptions that are not supported as to basis or to a verifiable source and pulls data from unidentified sources in order to come up with a speculative number of additional animals that will be raised to make up for those not treated with Baytril that die from air sacculitis. The testimony assumes that no other drug will work to treat the broilers, and this assumption results in the final numbers that Mr. Martin generates from there on out. Thus, Mr. Martin's entire testimony is speculative and unreliable. Further, as Mr. Martin is without even alleged qualifications to make assumptions of the efficacy of Baytril or any other alternative therapy, his calculations based on these assumptions are likewise unreliable. And, it is wholly speculative to assume that additional poultry would be raised to make up for any or all perceived production loss from the withdrawal of Baytril, therefore, his testimony is unreliable for that reason as well.

Most fundamentally, Mr. Martin's testimony is unreliable because it is contradicted by his own statement on this record. An earlier submission authored by Mr. Martin purported to be based on the same 1999 statistics and submitted to the Docket by cover letter dated February 16, 2001, and currently on the Docket as Bayer Exhibit B-1116, differs substantially from this testimony submitted on December 13, 2002, by Bayer. While one difference may be based on calculations of net increase of mortality/morbidity and condemnation vs. increase of mortality/morbidity and condemnation, Mr. Martin fails to explain (or even acknowledge) the differences in his two signed statements on this matter. For example:

- In Mr. Martin's earlier submission (B-1116, Martin letter, p.2), he estimates the economic impact of Baytril's removal from the market to be a loss of between $138 and $189 million dollars per year for broiler producers and $101.2 dollars per year for turkey producers; in his testimony (Martin WDT, Page 4, Lines 6-7), these figures are estimated at between $98.7 and $133.9 million dollars per year for broiler producers and $100.9 million dollars per year for turkey producers. The latter figure is nearly 8 million dollars off the alleged turkey loss that is estimated on Page 25 of the same testimony of this witness.

- In Mr. Martin's earlier submission, he estimates that condemnation cost for "airsac, sept. tox, infecious [sic] process, and condemn parts accounted for another 70.68 million dollars" (B-1116, at Page 4); in his testimony (Martin WDT, Page 4, Line 19), this figure is estimated at $139.07 million dollars. This unexplained substitution of one figure for another, when the substituted figure is increased by more than 68 million dollars calls into question the quality, and either the reliability or the truthfulness of Mr. Martin's testimony.

[2]In anticipation of Written Direct Testimony from Bayer and AHI on these financial issues, and to present countervailing evidence if financial issues are somehow deemed relevant, CVM chose to present economic evidence in the form of Dr. Nardinelli's testimony. However, CVM maintains that financial factors should not be considered in a new animal drug safety determination under the FDCA, and understands that if such factors are deemed irrelevant, that portion of Dr. Nardinelli's testimony may also be stricken from the record.

- In his earlier submission, Mr. Martin states that "[b]ased on 1999's National average cost per bird the broiler industry could lose between $112-149 million dollars annually." (B-1116 at Page 9; footnote omitted). In his testimony, Mr. Martin states, "Based on 1999's National average cost per bird the broiler industry could lose between $82-109 millions dollars annually." (Martin WDT, Page 11, Line 16; footnote omitted).

- In his earlier submission, Mr. Martin used a rule of thumb of $.0048 per live pound increased feed cost for every 1% increase in mortality (turkeys) and comes up with an increased feed cost of $44 million dollars annually (B-1116 at Page 17). In Mr. Martin's testimony, he states that the rule of thumb is $.0045 per live pound (Martin WDT, Page 19, Line 13) but then uses the same $.0048 per live pound (Martin WDT, Page 20, Line 5) to come up with a different figure for the increased annual feed cost of $52.3 million dollars (Martin WDT, Page 20, Line 9).

- In Mr. Martin's earlier submission to the record on behalf of Agrimetrics Associates, Inc., for Bayer's counsel, he estimates that "[w]ithout Baytril or a similar treatment it is Agrimetrics' estimate that the industry would suffer significant bird losses (4.6 million head) and higher production costs of $63.9 million per year. For the industry to maintain it's [sic] current level of production, additional housing and inferior [sic] structure would need to be developed. Assuming a cost of $8.04 per bird you can add another $37 million to the tally bringing the grand total to about $100.9 million annually." (B-1116, at Page 22). By contrast, in Mr. Martin's testimony he states, "[w]ithout Baytril or a similar treatment it is Agrimetrics' estimate that the industry would suffer significant bird losses (4.6 million head) and higher production costs of $71.3 million per year. For the industry to maintain it's [sic] current level of production, additional housing and inferior [sic] structure would need to be developed. Assuming a cost of $8.04 per bird you can add another $37 million to the tally bringing the grand total to about $108.3 million annually." (emphasis added) (Martin WDT, Page 24, Lines 17-22.) These unexplained alternations of Mr. Martin's numbers in successive versions demonstrate that this testimony is unreliable at best, and that at least one version of his statement is not true.

The discrepancies pointed out above show that either Mr. Martin's testimony lacks credibility, or his data are not supported by the record and are, therefore, unreliable, and for either of those reasons, his testimony should be stricken in its entirety. Even if Mr. Martin, Agrimetrics Associates, and Bayer were now to allege that one of Mr. Martin's allegations were true, and the others not, his testimony cannot be credited. If the first were true, why was the second filed with different numbers? If the second were true, why was there no explanation of such significant changes from the earlier submission? Both versions of his statements, B-1116 and his Written Direct Testimony should be stricken from this record as manifestly unreliable and untrustworthy.

The following are further examples of irrelevant, immaterial, and/or unreliable portions of Mr. Martin's testimony:

All portions listed above that are discrepant figures in both Mr. Martin's testimony and in Bayer's Exhibit B-1116.

Page 3, Lines 1-14 ("For the purposes of....processing cost."): This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 3, Lines 11-22 (all): This portion of Mr. Martin's testimony is unreliable. The testimony is based on a "phone survey" but the testimony lacks any description of, or data from, the survey, questionnaire, or methods used in conducting or analyzing the results of the survey. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 3, Lines 17-18 (all): The statement that the industry needs a drug like this because it works well when other drugs do not is not relevant to the issue of the hearing. Neither efficacy of the drug, nor comparative efficacy, of this drug to other drugs is relevant to a safety determination under the FDCA. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 3, Lines 19-20 (all): The cost of Baytril is not relevant to its safety. Therefore, this statement should be stricken from the record as irrelevant.

Page 3, Lines 21-22 (all): The efficacy of Baytril is not at issue in this hearing. Neither efficacy of the drug, nor comparative efficacy of this drug to other drugs, is relevant to a safety determination under the FDCA. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 4, Lines 1-4 (all): Mr. Martin does not have the necessary qualifications to make this statement. He is neither a veterinarian nor a microbiologist, nor does he support these statements with citations to reliable sources. Therefore, this portion of Mr. Martin's testimony should be stricken as unreliable.

Page 4, Lines 5-7 (all): This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant. Further, this testimony is unreliable. In Mr. Martin's earlier submission, he estimates the economic impact of Baytril's removal from the market to be a loss of between $138 and $189 million dollars per year for broiler producers and $101.2 dollars per year for turkey producers (B-1116, Page 2); in his testimony, this figure is estimated at between $98.7 and $133.9 million dollars per year for broiler producers and $100.9 million dollars per year for turkey producers (Martin WDT, Page 4, Lines 6-7). Therefore, the testimony is unreliable and should be stricken from the record.

Page 4, Lines 9-16 (all): This portion of Mr. Martin's testimony is unreliable in that allegations are unsupported by any traceable sources. Further, the interview questions, results

and methods are not detailed or referenced. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record in this hearing as unreliable.

Page 4, Lines 15-16 (all): The efficacy of, and need for, Baytril is not in issue at this hearing. Therefore, testimony concerning the need to have a drug such as enrofloxacin "that really works" is not relevant to the issue of the hearing and should be stricken from the evidentiary record as irrelevant.

Page 4, Lines 17-19 (all): This portion of Mr. Martin's testimony should be stricken for at least two reasons. First, as explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant. Second, these numbers are not supported by the record and are, therefore, unreliable. In Mr. Martin's earlier submission, he estimates that condemnation cost for "airsac, sept. tox, infecious [sic] process, and condemn parts accounted for another 70.68 million dollars." (B-1116, Page 4); in his testimony, this figure is estimated at $139.07 million dollars (Martin WDT, Page 4, Line 19).

Page 5, Lines 5-6 ("In most cases...in mortality."): The efficacy of Baytril is not in issue at this hearing. Therefore, this statement should be stricken from the evidentiary record as irrelevant.

Page 5, Lines 8-13 (all): This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 5, Lines 15-16 ("That impact placement schedules the possible need for more live production facilities to make up for the increased mortality and morbidity levels.") This portion of Mr. Martin's testimony is unreliable since it is an unintelligible sentence fragment, and should be stricken from the evidentiary record of the hearing.

Page 6, Lines 8-9 (all): The statistics concerning mortality, illness and condemnation are not relevant to the safety of Baytril, nor material to the determination in this matter, and should, therefore, be stricken from the evidentiary record. Table 3 should be stricken because as unreliable because an "attempt to simulate losses" is an unreliable foundation for testimony on its face.

Page 7, Lines 3-4 (all) and 8-end of Page (all): The statistics concerning mortality, illness and condemnation are not relevant to the safety of Baytril, nor material to the determination in this matter, and should, therefore, be stricken from the evidentiary record.

Page 8, Line 2 through Page 11, Line 17 (all): This portion of Mr. Martin's testimony is not relevant. It weaves back and forth between information on efficacy, mortality/illness/condemnation, and potential economic impact to the industry. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record as irrelevant. Further, it is based on un-cited and unverifiable assumptions and is, therefore, also unreliable.

Page 10 (all): The statistics concerning mortality, illness and condemnation are not relevant to the safety of Baytril, nor material to the determination in this matter, and should, therefore, be stricken from the evidentiary record. In addition, Table 4.1 does not appear to take into consideration alternative therapy or changes in husbandry or other industry practices. Therefore, the numbers in this chart are so speculative as to be unreliable.

Page 11, Lines 15-17: Economic impact on the industry is not relevant to the issue for hearing. Therefore, this statement is irrelevant and should be stricken from the record of this hearing. Further, this portion of Mr. Martin's testimony is unreliable. In his earlier submission, Mr. Martin states that "[b]ased on 1999's National average cost per bird the broiler industry could lose between $112-149 million dollars annually." (B-1116, Page 9)(footnotes omitted). In his testimony, Mr. Martin states, "Based on 1999's National average cost per bird the broiler industry could lose between $82-109 millions dollars annually." (Martin WDT, Page 11, Line 16)(footnotes omitted). Therefore, this portion of Mr. Martin's testimony, and B-1116, are contradictory and unsupported by the record and both should be stricken as unreliable.

Page 12, Lines 1-8: This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 12, Line 8 through Page 13, Line 9 (all): This portion of Mr. Martin's testimony is related to costs to the processing plant and therefore not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 13, Lines 10-17 (all): This portion of the testimony is not relevant or reliable. First, the testimony relating to economic worth is not relevant, for the same reasons as set out above. (Even if it were relevant, it is directly contradicted by this witness' prior statement submitted to this record, B-1116, Page 11 and is, therefore, unreliable.) Second, the testimony is unreliable because the calculation is based on a speculative number of additional animals that will be raised to make up for those not treated with Baytril that die from air sacculitis. Again, this calculation assumes that no other drug will work to treat the broilers, and that industry will not adjust processes to reduce the number of diseased birds, and bases assumptions that effect the final numbers on these speculative assumptions. Further, it is wholly speculative to believe that additional poultry would be raised to make up for any portion or all of the perceived production loss. For these reasons, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing.

Page 13, Line 18 through Page 14, Line 2 (all): This portion of Mr. Martin's testimony is related to costs to the processing plant and therefore not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 14, Lines 4-6 (all): For the reasons set out above, neither the need for such drug, efficacy of such drug, nor economic impact of withdrawal of the drug is relevant to the issue for hearing. Additionally, this testimony is unreliable as speculation unsupported by citations to reliable source. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of the hearing.

Page 14, Lines 12-15 (all): This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant. Further, this testimony is unreliable because it is not supported by the record. Mr. Martin's prior statement differs from his testimony (see Page 12 of B-1116, and Page 14 of this testimony).

Page 14, Line 17 ("The expected...and 16.9:1"): This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant. Further, this testimony is unreliable because it is not supported by the record. Mr. Martin's earlier submission differs from his testimony (see Page 12 of B-1116, and Page 14 of this testimony).

Page 15 (all): As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant. Further, this portion of the testimony is plainly unreliable. First, Baytril is not allowed as a food treatment (see first graph on Page 15). Second, the graphed values are contradicted by this witness' earlier charts in B-1116, Page 13. Therefore, in addition to be irrelevant, this testimony is unreliable and should be stricken from the record of this hearing.

Page 16, Lines 12-13 (all): These two sentences, based on an unverified, un-cited mystery survey of nineteen companies selected by unknown means, are patently unreliable and without visible support. Therefore, these two sentences should be stricken from the evidentiary record of this hearing.

Page 16, Page 14-15 (all): This sentence is immaterial to the issue of the hearing. It does not matter for issues of this hearing that the turkey industry first uses other drugs before using Baytril because of the high cost of Baytril. Therefore, this portion of the testimony should be stricken from the evidentiary record of this hearing.

Page 16, Lines 17-21 ("The trigger for...would have been devastating"): Efficacy of Baytril is not relevant to the issue of the hearing and this portion of Mr. Martin's testimony should, therefore, be stricken from the record. Further, what "would have been" is unreliable speculation, and this portion of the testimony should be stricken as unreliable.

Page 17, Lines 11-12 : The composites and the calculations based upon them, are unreliable because the algorithm for compositing and the regional statistics are both undisclosed and without citation to a reliable source.

Page 18, Lines 1-8 (all): Mortality and morbidity data are not relevant to the issue of this hearing. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing.

Page 18, Lines 9-15 ("Based on information...million head."): This portion of Mr. Martin's testimony is unreliable since it is based on speculation, and unverifiable, un-cited information. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing.

Page 18, Line 17 through Page 19 (all): As explained above, the costs and other economic factors are not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 19, Line 11 through Page 20, Line 9: This portion of Mr. Martin's testimony should be stricken as unreliable. In his earlier submission, Mr. Martin used a rule of thumb of $.0048 per live pound increased feed cost for every 1% increase in mortality (turkeys) and comes up with an increased feed cost of $44 million dollars annually (B-1116, Pages 17-18). In Mr. Martin's testimony, he states that the rule of thumb is $.0045 per live pound (Page 19, Line 13) but then uses the $.0048 per live pound (Page 20, Line 5) to come up with a figure of an increased feed cost of $52.3 million dollars annually. Therefore, not only is Mr. Martin's testimony unsupported by the record, it is also internally inconsistent. Therefore, this portion of the testimony should be stricken as unreliable.

Further, Lines 1-4 on Page 20 are not relevant or material. Mortality data are not related to the issue at hearing. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record as irrelevant and/or immaterial. And, even if they were relevant or material, these calculations are unreliable and affirmatively misleading, as they assume that serial percentage losses are all the same value, neglecting the "negative compounding" of declining-balance percentage reductions. For example, note that Mr. Martin alleging that he and his firm are experts in econometrics, assumes that a series of 10 days of 5 % losses would leave only half the flock, as if 5% of the 9th day flock was the same number as 5% of the first-day flock. If they are experts, this testimony is misleading. If not, it is simply incompetent. In either event, it should be stricken as unreliable.

Also, Lines 5-9 on Page 20 are not relevant. Costs and other economic factors are not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony, and everything based upon it, should also be stricken from the evidentiary record of this hearing as irrelevant.

Page 21 through Page 22 (all): As explained above, the costs and other economic factors are not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 22, Lines 1-3 (all): In a revealingly unreliable assumption, Mr. Martin assumes that the alleged industry loss should be calculated without tax. Therefore, this testimony, and any other testimony based on these numbers, should be stricken from the evidentiary record of this hearing as unreliable.

Page 23, Lines 1-4 (all): This portion of Mr. Martin's testimony is not relevant. Condemnation rate data are not related to the issue for hearing. Therefore, this portion of Mr. Martin's testimony should be stricken from the evidentiary record as irrelevant. Even if it were relevant, industry consensus is still unreliable without the actual interview questionnaire and responses. Therefore, this portion of the testimony is unreliable and should be stricken from the evidentiary record of this hearing.

Page 23, Lines 8-10 (all): Mr. Martin is neither a veterinarian nor a microbiologist and is therefore not qualified to make the statement at Lines 8-10. Therefore, this portion of Mr. Martin's testimony should be stricken as unreliable, unsupported speculation.

Page 23, Line 11 through Page 24, Line 3 ("One might consider...to consumers."): This portion of Mr. Martin's testimony should be stricken from the evidentiary record because it is not material to the issue of the hearing. Further, Mr. Martin is not a microbiologist or a food safety expert and, therefore, is not qualified to make this statement. Therefore, this portion of his testimony should be stricken based on reliability grounds as well.

Page 24, Lines 16-17 (In conclusion...facing producers."): Efficacy of Baytril is not relevant to the issue of the hearing and this portion of Mr. Martin's testimony should, therefore, be stricken from the record.

Page 24, Line 17 through Page 25, Line 3 ("Without Baytril...profit before tax."): This portion of Mr. Martin's testimony is not relevant to the issue of the hearing. As explained above, the economic impact on the industry is not related to whether the drug is safe. Therefore this portion of Mr. Martin's testimony should be stricken from the evidentiary record of this hearing as irrelevant. Further, in Mr. Martin's earlier submission, he estimates that "[w]ithout Baytril or a similar treatment it is Agrimetrics' estimate that the industry would suffer significant bird losses (4.6 million head) and higher production costs of $63.9 million per year. For the industry to maintain it's [sic] current level of production, additional housing and inferior [sic] structure would need to be developed. Assuming a cost of $8.04 per bird you can add another $37 million to the tally bringing the grand total to about $100.9 million annually." (B-1116, Page 22) In Mr. Martin's testimony (Page 24, Lines 17-22) he states, "[w]ithout Baytril or a similar treatment it is Agrimetrics' estimate that the industry would suffer significant bird losses (4.6 million head) and higher production costs of $71.3 million per year. For the industry to maintain it's [sic] current level of production, additional housing and inferior [sic] structure would need to be developed. Assuming a cost of $8.04 per bird you can add another $37 million to the tally bringing the grand total to about $108.3 million annually." Therefore, this portion of Mr. Martin's testimony is unsupported by the record and directly contradicted by the witness' own prior statement, it should be stricken from the evidentiary record of this hearing as unreliable.

The above examples demonstrate why Mr. Martin's entire testimony should be stricken from the evidentiary record of this hearing. Further, all attachments or exhibits to Mr. Martin's testimony should be stricken for the same reasons.

Steven R. Woodruff

CVM moves to strike the Written Direct Testimony of Mr. Woodruff in its entirety because his entire testimony is irrelevant and/or immaterial, and unreliable to the issue for hearing. The entire testimony rests on unreliable assumptions made first by Mr. Martin and used by Mr. Woodruff concerning the number of extra animals that would be produced to make up for any or all of the perceived loss in production. These numbers are speculative, and therefore unreliable, because there is no indication that the industry would produce the additional birds to make up for any or all of the perceived mortality if Baytril is withdrawn. Moreover, the numbers are speculative, and therefore unreliable, because the number of poultry that contract colibacillosis vary from year to year and decade to decade and cannot be reliably estimated.

Mr. Woodruff does not indicate whether his conclusions are based upon the actual wastewater discharges from the industry or upon wastewater discharges that *would* occur if each facility were in compliance with an National Pollutant Discharge Elimination System (NPDES) permit.[3] This is an important distinction because EPA and/or the State agency authorized to issue such wastewater discharge permits can set water quality limits to protect the environment.[4] Therefore, the conclusions reached by Mr. Woodruff based on these speculative figures are unreliable and should be stricken.

In addition, Mr. Woodruff bases his testimony on speculative testimony of Dr. Russell, accepting as fact Dr. Russell's unreliable and irrelevant and/or immaterial assertion that diseased birds lead to higher pathogen loadings.[5] For all the reasons set out elsewhere in this Memorandum, this testimony of Dr. Russell is irrelevant and immaterial, as well as unreliable, and should be stricken from the evidentiary record of this hearing. Therefore, Mr. Woodruff's testimony, based on this irrelevant, immaterial and unreliable testimony should likewise be stricken from the record.

Further, the only information that one could clearly glean from this testimony is the sheer magnitude of environmental damage caused by the poultry industry. The marginal increase in environmental burden attributed to the extra broilers that Mr. Martin estimates would be raised, and that Mr. Woodruff then bases his analysis on, is de minimis. The well recognized canon in common law of *de minimis non curat lex* (the law does not concern itself about trifles) should apply. Therefore, even if there were a slight increase in environmental burden and this were

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[3] Similarly, it is unclear whether the air emissions that Mr. Woodruff testifies about would be "actual" or permitted emissions.

[4] Section 302 of the Clean Water Act states, "Whenever, in the judgment of the Administrator....discharges of pollutants from a point source or group of point sources,...would interfere with the attainment or maintenance of that water quality in a specific portion of the navigable waters which shall assure protection of public health...effluent limitations...for such point source or sources shall be established which can reasonably be expected to contribute to the attainment of such water quality." 33 U.S.C. §1321.

[5] See arguments for striking Dr. Russell's testimony elsewhere in this Memorandum.

deemed to be relevant to the seemingly unrelated issue at hearing, this testimony only shows that any extra pollutant loading would be de minimis and therefore any testimony concerning such extra loading is not material since it will not assist the Administrative Law Judge in making an ultimate decision in this matter.

In addition to requesting that Mr. Woodruff's testimony be stricken in its entirety, CVM requests that all attachments to, and exhibits cited within, Mr. Woodruff's testimony be stricken for the same reasons.

The following are examples of irrelevant, immaterial, and/or unreliable portions of Mr. Woodruff's testimony:

Page 6, Line 17 through Page 18, Line 3 (all): This portion of Mr. Woodruff's testimony is irrelevant and/or immaterial to the issue for hearing. Whether the poultry industry consumes natural resources and produces wastes does not relate to the issue of whether Baytril is safe, and will not assist the Administrative Law Judge in such a determination.

Page 7, Lines 4- 20 ("The withdrawal of the NADA....and soybean production."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 8, Lines 1-10 ("Summary of Most Significant...processing plants."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 8, Lines 10-18 (Processing plants rely on....that follow on the line (Russell 2002)."): This portion of Mr. Woodruff's testimony is speculative and therefore unreliable because it assumes, among other things, that there can be no changes in the husbandry or processing (manual vs. mechanical evisceration, more space between chickens on the evisceration line, etc.) of poultry to avoid excess fecal contamination. Therefore, this portion of the testimony should be stricken from the evidentiary record of this hearing.

Page 8, Line 19 through Page 9, Line 5 ("To handle the....before HACCP until today..."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and

testified to) by Mr. Woodruff that utilizes inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 9, Lines 5-8 ("Industry sources...WATT survey."): This portion of Mr. Woodruff's testimony is irrelevant and/or immaterial. Increases of water usage attributed to the implementation of HACCP is not relevant or material to whether Baytril is now shown to be safe.

Page 9, Line 14 through Page 10, Line 5 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 10, Line 6 through Page 12, Line 16 (all): This portion of Mr. Woodruff's testimony is irrelevant to the issue of the hearing. Whether there is a drought and where it might be are both irrelevant to the issue of whether Baytril has been shown to be safe. Further, this portion of the testimony is unreliable. Mr. Woodruff has not presented any qualification as to his ability to describe or predict weather patterns. Therefore, this portion of the testimony should also be stricken because it is unreliable.

Page 12, Line 17 through Page 13, Line 3 (all): Water reuse programs are not relevant to the safety of Baytril. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the record on relevancy grounds.

Page 13, Lines 4-12 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 13, Lines 13-20 (all): The wastewater discharge practices of poultry processing plants is not relevant to the issue of the hearing. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the record of this hearing.

Page 13, Line 21 through Page 15, end of chart (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 15, Line 2 through Page 20, Line 5 (all): This portion of the testimony is not relevant or material to the issue of the hearing. The characterization and composition of wastewater generated and discharged by poultry processing plants is not relevant to whether Baytril has been shown to be safe and will not assist the Administrative Law Judge in a determination of the issue for hearing.

Page 20, Lines 6-11 (all): This portion of Mr. Woodruff's testimony is unreliable, irrelevant and immaterial. Lines 7-9 ("Many of ...were withdrawn") are speculative, based on assumptions that additional pollutants will be generated if Baytril is withdrawn. Further, Lines 9-11 are not backed up with any cites to sources of this information.

Page 20, Line 12 through Page 22, Line 3 (all): This portion of the testimony is irrelevant and immaterial to whether Baytril is shown to be safe and, therefore, this portion of the testimony should be stricken on relevancy grounds. Further, Page 21, Lines 6-8 and Page 22, Lines 1-3 are speculative because they assume as fact the speculative numbers generated by Mr. Martin and relied upon by Mr. Woodruff in his testimony. Therefore, in addition to striking these portions of testimony as irrelevant, they should also be stricken since they are unreliable.

Page 22, Lines 4-12 (all) and Page 23, Lines 5-8 ("Removing Baytril...food supply."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 22, Line 13 through Page 23, Line 5 ("This issue was discussed...in North Georgia."): The water quality of municipal water systems in North Georgia is not relevant or material to the issue of whether Baytril is safe. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the evidentiary record of the hearing.

Page 23, Lines 10-13 ("Another serious consequence...ground water."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 23, Lines 13-20 (Many of these chemicals...in processing operations.") Testimony on the chemicals used in poultry processing is not relevant or material to the issue of whether Baytril is safe.

Page 23, Line 21 through Page 25, Line 13 (all): Testimony that the "broiler industry saw a dramatic increase in the use of sanitation and pathogen reduction chemicals as a result of

HACCP implementation" is not relevant or material to the issue at hearing. Further, the testimony on the chemicals used in poultry processing is not relevant or material to the issue of whether Baytril is safe. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the record.

Page 25, Line 14 through Page 26, Line 2 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 26, Line 3 through Page 27, Line 6 (all): The testimony regarding ammonia emitted from animal agriculture is not relevant or material to the issue of whether Baytril is shown to be safe.

Page 27, Line 7 through Page 29, Line 8 (""Increased Particulate Matter:...by-product materials generated."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 29, Lines 8 –13 ("All segments...such as scalders."): The testimony about the kind of natural resources used by the poultry industry is not relevant to the issue at hearing; therefore, this portion of Mr. Woodruff's testimony should be stricken from the evidentiary record of this hearing.

Page 29, Line 14 through Page 30, Line 12 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 30, Line 13 through Page 33, Line 7 (all): This testimony on the constituents of air pollution is not relevant or material to the issue for hearing. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the evidentiary record of this hearing.

Page 33, Line 8 through Page 34, Line 9 ("Usage of Baytril...tons of mortality."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff

that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 34, Line 9 through Page 36, Line 5 ("According to a recent survey...disease outbreaks."): This testimony should be stricken on several grounds. First, it is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable. Additionally, Lines 9-12 pertain to an unidentified, un-cited study. In addition, this portion of the testimony is not relevant or material to whether Baytril is shown to be safe. Therefore, this portion of the testimony should be stricken from the record of this hearing as unreliable, irrelevant and immaterial.

Page 37, Line 1 through Page 38, Line 6 (all): This portion of the testimony is not relevant or material to the issue for hearing and should be stricken from the evidentiary record of this hearing.

Page 38, Lines 7-14 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 38, Line 15 thorugh Page 39, Line 14 (all): This testimony is not relevant or material to the issue of whether Baytril has been shown to be safe. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the evidentiary record of the proceeding.

Page 39, Line 15 through Page 40 Line 10 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 40, Line 11 through Page 41, Line 16 ("Industrial wastewater...heavy metals and BOD, COD, etc") This portion of the testimony is not relevant or material to the issue of the hearing. Testimony concerning, among other things, the EPA Biosolids Rule and DAF skimmings is not relevant to the safety of Baytril and will not assist the Administrative Law Judge in making a determination on the issue for hearing.

Page 42, Lines 1-9 ("Use of Baytril...poultry processing plants."): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 42, Line 14 through Page 43, Line 10 (All): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable. Further, the testimony about the expected increase and the attempts by industry to compensate for these increases is pure speculation and should be stricken as unreliable. Also, the testimony that "[T]he regulatory enforcement actions that will be taken as a result of these suspected future permit violations will require the implementation of treatment system upgrades" is speculative and unreliable. Finally, none of this testimony is relevant or material to the issue for hearing. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the evidentiary record of this hearing.

Page 43, Line 11 thorugh Page 44, Line 4 (all): The testimony concerning Class V underground injection wells is not relevant or material to the issue of whether Baytril has been shown to be safe. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the record.

Page 44, Lines 5-14 (all): This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 44, Line 15 through Page 45, Line 8 (all): The use of pesticides to grow corn and soy meal is not relevant or material to the issue of the hearing. And, to the extent this testimony concerns the additional pesticides that may be used to grow additional feed for the speculative number of additional animals, this portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 45, Line 6 through Page 46, Line 14 ("6. Injuries, Illnesses, and Fatalities...transportation related.") This portion of Mr. Woodruff's testimony is unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 46, Line 14 through Page 47, Line 8 ("The average fatality rate...in fatalities"): This portion of Mr. Woodruff's testimony is not relevant or material to the issue of whether Baytril has been shown to be safe.

Page 47, Lines 10-20 (all): This testimony is speculative and unreliable. Further, if Mr. Woodruff's earlier testimony is stricken for the reasons set out in this memorandum, then his conclusion based on the stricken testimony should likewise be stricken.

Page 48, Line 6 through Page 51, Line 3: (The elimination of...zero tolerance requirements"): This portion of Mr. Woodruff's testimony is not material to the issue of the hearing and will not assist the Administrative Law Judge in a determination of whether Baytril is now shown to be safe. Therefore, this portion of Mr. Woodruff's testimony should be stricken from the evidentiary record of this hearing.

Page 51, Lines 4-9 (all), and 19-21 (all): These portions of Mr. Woodruff's testimony are unreliable. Mr. Woodruff's testimony is based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Page 51, Lines 10-14 (all) and 15-18 (all): These portions of Mr. Woodruff's testimony are not relevant or material to the issue for hearing and should be stricken from the evidentiary record of this hearing.

Page 52, Lines 10-13 ("Judicious use of Bautril...poultry industry."): This portion of Mr. Woodruff's testimony is unreliable. It makes conclusions based on testimony subject to this motion to strike (on reliability grounds, because the testimony is based on data provided by Mr. Martin which itself is unreliable) and should likewise be stricken from the record.

Attachment #1 and #2: These attachments to Mr. Woodruff's testimony are unreliable. The information in the attachments and the model outputs are based on inputs generated by Mr. Martin that are unsupported, unverifiable and otherwise unreliable, including the speculation that the industry would produce additional birds if the approval of the NADA for Baytril were withdrawn. Therefore, all of the data generated (and testified to) by Mr. Woodruff, including

Attachment #1 and #2, that utilize inputs from Mr. Martin's testimony or his earlier submission (B-1116) should be stricken from the evidentiary of this hearing as unreliable.

Attachment #3: This attachment consists of a memorandum from Mr. Martin to Mr. Woodruff providing estimates on replacement breeders and transportation issues. The numbers provided are unreliable since there is no explanation of where the numbers came from, how they were generated, etc. Therefore, this entire attachment should be stricken from the record as unreliable.

Attachment #4: This attachment consists of a memorandum from Mr. Martin to Mr. Woodruff providing additional cost information. The information provided in this attachment should be stricken since there is no explanation of where the numbers came from or how they were generated. Further, to the extent the numbers purport to be utility costs, the attachment is not relevant nor material to the issue of the safety of Baytril. Therefore, Attachment #4 should be stricken from the evidentiary record of this hearing as unreliable, irrelevant and immaterial.

The above examples demonstrate why Mr. Woodruff's entire testimony, and all attachments thereto, should be stricken from the evidentiary record of this hearing.

Robert H. Harris

CVM moves to strike the Written Direct Testimony of Dr. Harris in its entirety because his testimony is irrelevant and immaterial to the ultimate issue in the hearing, namely, whether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved. Further, the testimony is so speculative as to be unreliable.

The environmental issues presented in Dr. Harris' testimony are irrelevant to the issue of the hearing. The issues presented in Dr. Harris' testimony are so far outside the items that could be rationally included in a consideration of human health risks/benefits in a decision regarding the withdrawal of approval for a new animal drug application, that his testimony is irrelevant.[6] Moreover, to the extent that any of the so-called "benefits" described by Dr. Harris could be considered relevant to the issue of the hearing, this testimony is immaterial since it will not help the Administrative Law Judge make a safety determination with respect to Baytril.

Further, the Harris testimony is not material to a finding on the ultimate issue at hearing because the so-called "benefits", if reliably predicted (see below) are de minimis. Even if Dr. Harris' testimony were accepted, the only facts that are clear are that the resources currently consumed by, and impact from, the poultry industry (from the hatchery to the slaughterhouse and

[6] If these factors were a required part of CVM's determination of safety in a review of a new animal drug application, then CVM would need to require all sponsors of new animal drug applications to include such "life cycle" evaluations in their environmental assessments required as part of a new animal drug application. Since these "life cycle" assessments have not traditionally been required for new animal drug application, and were not required for the Baytril approval, they should not be imposed nor considered relevant for evaluating any potential impact from the withdrawal of Baytril.

everywhere in between) are astronomical. The marginal increase in environmental burden attributed to the extra broilers that Dr. Harris estimates would be raised is de minimis. The well recognized canon in common law of *de minimis non curat lex* (the law does not concern itself about trifles) should apply. Therefore, even if there were a slight increase in environmental burden and this were deemed to be relevant to the seemingly unrelated issue at hearing, this testimony is immaterial since it will not assist the Administrative Law Judge in making an ultimate decision in this matter.

Further, this testimony should be stricken in its entirety because it is premised on unreliable information supplied by Mr. Martin's and Mr. Woodruff's testimony. As demonstrated below in more detail, these data are so speculative as to be unreliable. Therefore, all testimony that bases opinion on this data should similarly be stricken from the evidentiary record because it, too, is unreliable. For example, the mortality data presented by Dr. Harris on Page 4, Line 21 through Page 5, Line 6, and attributed to Mr. Woodruff and Mr. Martin (Agrimetrics), is based on an estimation of the number of broilers and turkeys that will need to be raised to make up for those that die without the use of Baytril. However, the data from Mr. Martin and Mr. Woodruff are unreliable in several respects. First, there is no clear basis for Mr. Martin's original estimation and therefore the numbers are unreliable and should be stricken. Second, the numbers supplied by Mr. Martin and relied upon by Dr. Harris are speculative because they appear to be based on current conditions without the use of Baytril *or any other antimicrobial* or any other husbandry or processing change in industry practice. There is no reason to believe that these numbers cannot be reduced based on alternative drug therapy or better husbandry and/or slaughterhouse practices. Therefore, the wholly speculative nature of this testimony makes it unreliable. Third, the testimony is so biased as to be unreliable. Dr. Harris purports to conduct an assessment of the risks associated with the withdrawal of Baytril, but he leaves out of his assessment all of the environmental risks associated with the production and distribution of Baytril, as well as the more concrete issue of the fate and transport of antimicrobial resistant bacteria in the environment.[7] For these three reasons, Dr. Harris' testimony should be stricken in its entirety based on reliability concerns.

Additionally, the numbers used in Dr. Harris' testimony are speculative, and therefore unreliable, because there is no indication that the industry would produce the additional birds to make up for any or all of the perceived mortality if Baytril is withdrawn. Moreover, the numbers are speculative, and therefore unreliable, because the number of poultry that contract colibacillosis vary from year to year and decade to decade and cannot be reliably estimated.

In addition to requesting that Dr. Harris' testimony be stricken in its entirety, CVM requests that all attachments to, and exhibits cited within, Dr. Harris' testimony be stricken for the same reasons.

The following are examples of irrelevant, immaterial, and/or unreliable portions of Dr. Harris' testimony:

Page 3, Lines 20-24 ("Conversely, the direct...food-related illnesses."): This portion of Dr. Harris' testimony is irrelevant and unreliable. First, efficacy ("millions of birds are saved and

[7] One could argue that if this testimony is considered relevant, then the environmental record of the entire poultry industry would likewise be relevant.

their suffering reduced by the therapeutic use of Baytril") is irrelevant to the issue of whether the drug is safe. Further, testimony regarding the number of infected and diseased birds that are processed and any concomitant decrease in the prevalence of food-related illness is unreliable because it assumes that the poultry industry will not attempt to control pathogens in its products in alternative ways.

Page 4, Lines 4-20 (all): This portion of Dr. Harris' testimony should be stricken since it is not relevant to a determination in this hearing. This portion of Dr. Harris' testimony provides an overview of the environmental regulation of the poultry industry and other related issues. The current hearing, however, is an FDA hearing on the safety of a new animal drug, not a hearing on the environmental pollution from the poultry industry, therefore, this portion of Dr. Harris' testimony is irrelevant and should be stricken from the record of this hearing (See footnote 7).

Page 4, Line 21 through Page 5, Line 2 ("It has been estimated...produce these broilers."): This portion of Dr. Harris' testimony should be stricken from the evidentiary record because it is based on unreliable data provided by another witness, Mr. Martin. As argued in more detail elsewhere in this Memorandum, Mr. Martin's testimony makes assumptions that are not identified and pulls data from unidentified sources in order to come up with a speculative number of additional animals that will be raised to make up for those not treated with Baytril that die from air sacculitis. The testimony assumes that no other drug will work to treat the broilers, and bases assumptions that effect the final numbers on that assumption (which the witness is not qualified to make). Further, it is wholly speculative to believe that additional poultry would be raised. No one can predict what consumers or the industry will or will not do if faced with a less than 1% drop in production. Therefore, all testimony of Dr. Harris' that relies on the earlier speculative and unreliable numbers generated by Mr. Martin should be stricken from the evidentiary record as unreliable.

Page 5, Lines 2-4 ("The efficacy of Baytril...natural resources"): The efficacy of Baytril is not relevant to the issue of whether the drug is safe. Further, whether the poultry industry "operates in an environmentally efficient manner, avoiding the generation of this additional waste and the increased use of natural resources" is wholly irrelevant and immaterial to the issue of whether the drug is safe. Therefore, this portion of Dr. Harris' testimony should be stricken from the evidentiary record of the hearing based on the grounds that it is both irrelevant and immaterial.

Page 5, Lines 4-23 (all): This portion of Dr. Harris' testimony is based again on the speculative data from another witness. In this case, Dr. Harris uses Mr. Woodruff's analysis to come up with a range of estimations. Unfortunately, Mr. Woodruff bases his analysis on speculative data supplied by Mr. Martin, so any reliance on Mr. Woodruff's analysis by Dr. Harris is unfounded and any resulting testimony is unreliable for the same reasons as explained above. Further, the testimony is immaterial because the net effect on the environment from any extra broilers raised and processed is de minimis.

Page 6, Lines 3-10 ("For example, the...some time now."): This portion of the testimony is immaterial and unreliable. First, the testimony has nothing to do with the safety of Baytril based on antimicrobial resistance concerns and therefore will not assist in a determination of the issue for hearing. Therefore, this testimony should be stricken as immaterial. Second, the

testimony seems to be based on estimates by Mr. Martin and Mr. Woodruff. For reasons explained above, this data are not reliable and should, therefore, be stricken from the evidentiary record of this hearing.

Page 7, Lines 6-19 (all): The portion of testimony addressing a decrease in gastrointestinal illness should be stricken from the record as unreliable. This figure is speculative as it is based on estimates from Mr. Woodruff's testimony which were made using the unreliable numbers generated by Mr. Martin in his testimony. Further, it is unreliable because it purports to extrapolate an estimate of illness in a unique river basin (Page 7, Line 14) into a nationwide statistic (Page 7, Line 18). Thus, this portion of Dr. Harris' testimony is unreliable and should be stricken from the record. Further, this testimony is immaterial because it does not help reach a determination of the safety of enrofloxacin based on antimicrobial safety concerns.

Page 7, Line 20 through Page 12, Line 3 (all): This portion of Dr. Harris' testimony should be stricken as irrelevant, immaterial, and unreliable. It is irrelevant because it is so far removed from the issue of the hearing; immaterial because testimony concerning cancer risk from exposure to disinfection by-products will not assist the Administrative Law Judge in making a determination of whether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved; and, unreliable because the entire argument rests on a series of estimates which are ultimately based on the unreliable assumptions made by Mr. Martin in his testimony regarding the speculation on the additional number of broilers that would be raised if the new animal drug approval for Baytril is withdrawn. Therefore, this portion of Dr. Harris' testimony should be stricken from the evidentiary record of this hearing.

Page 12, Lines 4-15 (all): The workplace injury data presented in this portion of Dr. Harris' testimony is not relevant to the issue of the hearing and should be stricken from the record.

Page 12, Lines 16-17 ("The efficacy....poultry industry"): This testimony is irrelevant because it concerns the efficacy of the drug. The efficacy of the drug is not relevant to the safety determination to be made in this hearing. Therefore, this portion of Dr. Harris' testimony should be stricken as irrelevant.

Page 12, Lines 17-20 ("First, an annual....withdrawn (Martin 2001)(B-1116)."), and Page 12, Lines 20-22 ("An increase...the birds."): These portions of the testimony are unreliable because they are based on the unreliable assumptions made by Mr. Martin in his testimony regarding the speculation on the additional number of broilers that would be raised if the new animal drug approval for Baytril is withdrawn. Therefore, these portions of Dr. Harris' testimony should be stricken from the evidentiary record.

Page 12, Line 22 through Page 13, Line 2 ("Second...fatalities."): This portion of the testimony should be stricken because it is unreliable. It assumes that no other drug will be effective and that other changes cannot be made in animal husbandry/processing to avoid the processing of sick birds. Further, the testimony assumes the figures that Mr. Martin puts forth,

which themselves are unreliable. Therefore, this testimony is so speculative as to be unreliable and should be stricken from the evidentiary record of this hearing. Moreover, this portion of the testimony is not material to the issue of whether Baytril is safe. Therefore, this section of the testimony should also be stricken as immaterial.

Page 13, Lines 3-14 (all): This portion of the testimony is unreliable because it is based on the unreliable assumptions made by Mr. Martin in his testimony regarding the speculation on the additional number of broilers that would be raised if the new animal drug approval for Baytril is withdrawn. Therefore, this portion of Dr. Harris' testimony should be stricken from the evidentiary record as unreliable

Page 13, Lines 19-21 ("One of ...must be processed (Martin 2001) (B-1116)." Again, this testimony is based on the testimony of Mr. Martin which is also subject to this Motion to Strike. As stated above, the testimony assumes that no other drug or alternative practices will work to treat the broilers or reduce illness. Therefore, this portion of Dr. Harris' testimony that relies on the earlier speculative and unreliable numbers generated by Mr. Martin should be stricken from the evidentiary record as unreliable.

Page 14, Lines 3-7 (all): This paragraph is not relevant to the issue of the hearing and should be stricken from the evidentiary record.

The above examples demonstrate why Dr. Harris' entire testimony should be stricken from the evidentiary record of this hearing. Further, any attachments or exhibits to Dr. Harris' testimony should be stricken for the same reasons.

Paul B. Iannini

The Center does not move to strike any portion of Dr. Iannini's Written Direct Testimony.

Mark S. Pasternack

The Center does not move to strike any portion of Dr. Pasternack's Written Direct Testimony.

Manfred J. S. Kist

The following portions of Dr. Kist's testimony should be stricken from the evidentiary record of this hearing:

Page 4, Lines 9-11 ("Nevertheless, the estimates are....have been noticed."): This testimony is so speculative as to be unreliable. Dr. Kist makes the assumption that those infections that lead to death would be so severe as to be noticed. However, this assumption is not supported by any facts in evidence. Therefore, this statement is so speculative as to be unreliable and should be stricken from the record.

Page 10, Line 15 through Page 11, Line 3 ("To collect... was mentioned."): This portion of the testimony describes the results of a questionnaire that supposedly was sent to twelve different countries asking for the recommended first and second-line treatment regimes of C. jejuni and C. coli. However, the testimony fails to indicate who sent the questionnaire, what the exact questions and answers were, and how many of the twelve countries responded. Therefore, this information is unreliable and should be stricken from the evidentiary record on that ground.

James W. Patterson

CVM moves to strike Dr. Patterson's testimony in its entirety. Dr. Patterson's testimony is immaterial to the issue of the hearing. The question for hearing is not whether there are sources of fluoroquinolone-resistant Campylobacter other than poultry. Rather, the issue for hearing, "whether new evidence shows that enrofloxacin is not now shown to be safe for use under the conditions of use upon the basis of which the application was approved" includes the question of "whether fluoroquinolone-resistant Campylobacter spp. in poultry are transferred to humans and whether they contribute to fluoroquinolone-resistant Campylobacter infections in humans" (emphasis added). Therefore, Dr. Patterson's testimony, and any exhibits and attachments thereto, are not material to the determination of the issue for hearing and should be stricken from the evidentiary record of this hearing in its entirety.

Michael C. Robach

CVM moves to strike Mr. Robach's testimony in its entirety. This testimony is repetitive and therefore, the entire testimony should be stricken from the evidentiary record. Similar testimony appears in Drs. Prucha's and Russell's and Tompkins' testimony. The repetitiveness of these testimonies is evident from each witness' description of their own testimony:

Mr. Robach: [Robach WDT, Page 3, Lines 7-11]:
"For the purposes of this administrative hearing, I have been asked to examine and testify about the following issues: the importance of microbial food safety in general, HACCP, the importance of pathogen control in broiler/turkey processing, HACCP critical control points in broiler/turkey processing, the impacts on food safety if Baytril is no longer available and general regulatory control of fluoroquinolone-resistance *Campylobacter*."

Dr. Russell: [Russell WDT, Page 3, Lines 5-9]:
"For the purpose of this administrative hearing, Bayer requested that I examine and testify about the following issues: general poultry processing procedures/practices; the importance of pathogen control in broiler processing; identification of critical control points in broiler processing and the impact on processed broilers if Baytril enrofloxacin is no longer available to treat *E. coli* infections in broiler houses."

Dr. Prucha: [Prucha WDT, Page 3, Lines 3-8]:
"For the purpose of this administrative hearing, I have been asked to examine and testify about the following issues: the importance of microbial food safety in general; the HACCP

Program: the Food Safety Inspection Service (FSIS) in general; the importance of pathogen control in broiler/turkey processing; HACCP critical control points in broiler/turkey processing; the FSIS/Poultry Products Inspection Act as related to this matter; and overall regulatory control of fluoroquinolone resistant *Campylobacter* as a food safety issue."

Dr. Tompkin: [Tompkin WDT, Page 2, Line 20 - Page 3, Line 3]:

"For the purpose of this administrative hearing, I was asked to examine and testify about the following issues: the importance of microbial food safety; the HACCP Program for control of food borne pathogens; the importance of pathogen control in broiler/turkey processing; HACCP critical control points in broiler/turkey processing; the impacts on food safety if enrofloxacin is no longer available, including the impact on broiler pathogen load; assessing the risk; and regulatory control of fluoroquinolone-resistant *Campylobacter*."

Alternatively, CVM moves to strike the portions of Mr. Robach's testimony identified below as irrelevant, immaterial, unreliable, or repetitive to the issue for this hearing. The following provides more detail about why CVM believes, at a minimum, certain portions of Mr. Robach' s testimony should be stricken from the evidentiary record.

Page 3, Line 12 through Page 4, Line 4 (all): The membership and purpose of the National Advisory Committee on Microbiological Criteria for Foods has no bearing on the issue of this hearing as set out by the Commissioner in the Notice of Hearing. Therefore, this portion of Mr. Robach's testimony is irrelevant and should be stricken from the record.

Page 4, Lines 10-14 "Campylobacteriosis...at all.": This testimony is repetitive. Dr. Russell testified similarly (see Page 10, Lines 1-6 of Dr. Russell's testimony, B-1912). Therefore this portion of Mr. Robach's testimony should be stricken as repetitive.

Page 5, Lines 8- 16 (all): Mr. Robach is not a medical doctor and does not possess the expertise necessary to offer this portion of his testimony. Therefore, this testimony should be stricken on reliability grounds.

Page 6, Lines 1-12 "Unpasteurized milk...hygiene practices.": This portion of Mr. Robach's testimony is immaterial to the issue of the hearing. The fact that there are other sources of Campylobacter other than poultry will not aid in a determination of the issue in the hearing. For this reason, this portion of the testimony should be stricken from the evidentiary record as immaterial.

Page 6, Line 17 through Page 7, Line 1 "It is not... human consumption": This portion of the testimony is not relevant to the issue as set forth by the Commissioner in the Notice of Hearing. Whether or not USDA considers pathogens to be adulterants has no bearing on whether a new animal drug is shown to be safe under the FDCA. Therefore, this portion of Mr. Robach's testimony should be stricken from the evidentiary record as irrelevant.

Page 7, Lines 1-18 "It is understood...surface water.": This portion of the testimony is irrelevant. Cooking and hygiene suggestions are not relevant to the issue of the hearing. Moreover, Mr. Robach does not present evidence on what people <u>actually</u> do, but rather merely

on suggestions on what they should do. This information should be stricken from the evidentiary record as irrelevant.

Page 8, Line 3 through Page 9, Line 8 (all): Mr. Robach is not an epidemiologist, nor has he asserted any specific expertise in epidemiology. Therefore, Mr. Robach is not qualified to testify to the statements in this portion of his testimony. Therefore, this portion of the testimony should be stricken from the evidentiary record as unreliable.

Page 8, Lines 10-13 (all) ": This portion of Mr. Robach's testimony is not material because the timeframe of the data is prior to approval of enrofloxacin for use in poultry in the United States. Therefore, this portion of the testimony should be stricken from the evidentiary record as immaterial.

Page 8, Lines 22 through Page 9, Line 8 (all): This portion of the testimony addresses foodborne pathogens other than Campylobacter. Therefore, this portion of the testimony should be stricken from the evidentiary record as irrelevant and as immaterial.

Page 9, Line 16 through Page 10, Line 17 (all): This information on the HACCP program is not relevant or material to the issue of the hearing and should therefore be stricken from the evidentiary record. Further, Drs. Russell, Prucha and Tompkin all testify similarly to the HACCP program, so this testimony is repetitive and should be stricken.[8]

Page 11, Lines 3-4 ("Salmonella... transmitted") and Page 11, Line 21 through Page 12, Line 1 ("Unless there is...plant"), and Page 12, Lines 3-5 ("Salmonella...the egg"): These statements regarding Salmonella are not relevant to the issue of the hearing and should be stricken from the evidentiary record.

Page 12, Lines 7-13 (all): This testimony on indicator organisms is not relevant or material to the ultimate question to be determined by this hearing. Therefore, this portion of the testimony should be stricken as irrelevant and as immaterial.

Page 12, Line 14 through Page 13, Line 16 (all): This testimony is not relevant or material to the ultimate question to be determined by this hearing. Therefore, this portion of the testimony should be stricken as irrelevant and as immaterial.

Page 13, Lines 21-24 ("Competitive exclusion....controls."): This statement deals with competitive exclusion products with respect to reducing the incidence of Salmonella. This issue is not relevant or material to whether Baytril is now shown to be safe for use under the

[8] While CVM believes that a brief description of HACCP is appropriate (see Minnich, WDT, paragraphs 27 and 28 beginning at page 10, line 8) in order to place it in context for any testimony offering HACCP as a theory as to why the incidence of campylobacteriosis (although not fluorquinolone-resistant campylobacteriosis) has decreased in recent years, CVM believes that the kind of detailed history and description of the HACCP program offered by Mr. Robach and other Bayer or AHI witnesses will not assist the ALJ in making a determination concerning the safety of Baytril, and is therefore immaterial.

conditions approved for use in poultry, and therefore this statement should be stricken from the record.

Page 13, Line 24 through Page 14, Line 4 ("This is because....contamination"): Because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of conformity to size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing.

This testimony is also speculative. Bayer ignores the fact that the mechanical process is optional: chickens and turkeys can both be eviscerated manually if the industry is willing to take the time and resources to do it. Further, the prediction of increased pathogens is also speculative because it assumes the industry will not attempt to protect public health by reducing pathogens as much as possible in other ways. Therefore, this testimony should be stricken since it is so speculative as to be unreliable.

This testimony is repetitive. Drs. Prucha, Russell and Tompkin testify similarly. Therefore, for all these reasons, this portion of Mr. Robach's testimony should be stricken from the evidentiary record.

Page 15, Lines 1-17 (all), and Page 15, Lines 19-21 ("The study...carcasses."): Because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of conformity to size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing.

This testimony is also speculative. Bayer ignores the fact that the mechanical process is optional: chickens and turkeys can both be eviscerated manually if the industry is willing to take the time and resources to do it and if consumers want poultry enough to pay for it, manually processed. Further, the prediction of increased pathogens is also speculative because it assumes the industry will not attempt to protect public health by reducing pathogens as much as possible in other ways. Therefore, this testimony should be stricken because it is so speculative as to be unreliable.

This testimony is repetitive. Drs. Prucha, Russell and Tompkin testify similarly. Therefore, for all these reasons, this portion of Mr. Robach's testimony should be stricken from the evidentiary record.

Finally, this testimony is not reliable because Mr. Robach has no firsthand knowledge of the study and Dr. Russell, who already attempts to testify to this study (see B-1912, and arguments in this memorandum concerning Dr. Russell's testimony) would be in a better position to so testify if such testimony is entered into the record. For all of these reasons, this section of Mr. Robach's testimony should be stricken from the evidentiary record.

Page 15, Lines 18-19 ("Enrofloxacin...air sacculitis"): This statement goes toward the efficacy of enrofloxacin to treat air sacculitis. This issue is not relevant to the safety of Baytril and, therefore, should be stricken from the evidentiary record as irrelevant.

Page 16, Lines 7- 15 (all): This testimony is not relevant. The FDCA does not require that CVM or FDA conduct a risk assessment before a new animal drug approval is withdrawn. Furthermore, this testimony is irrelevant because it deals with *microbial* risk assessment not *antimicrobial* resistance risk assessment. Therefore, this portion of Mr. Robach's testimony should be stricken from the evidentiary record as irrelevant.

Page 16, Lines 17-21 ("The regulatory issue...products"), and Page 16, Line 22 through Page 17, Line 3 ("The poultry industry...public health"): None of this testimony is relevant or material to the issue of this hearing. For example, regardless of the witness' opinion that various agencies should be involved and that the issue to address is one of enteric pathogen control not just fluoroquinolone resistant Campylobacter control, this testimony is not relevant to the issue of safety. This portion of the testimony does not aid the Administrative Law Judge in making the ultimate decision on the issue of the hearing as set out by the Commissioner in the Notice of Hearing. Therefore, this portion of Mr. Robach's testimony should be stricken from the evidentiary record as irrelevant and immaterial.

Page 17, Lines 7-17 ("The industry...safety continuum"): For the reasons cited above, these conclusions should likewise be stricken from the evidentiary record.

Scott Russell

CVM moves to strike the portions of Dr. Russell's testimony set out below. CVM notes that similar testimony appears in Mr. Robach's testimony and Drs. Prucha's and Tompkins' testimony. The repetitiveness of these testimonies is evident from each witness' description of their own testimony as set out above.

Page 6, Line 10 through Page 7, Line 22 (all): This portion of the testimony addresses FSIS regulatory requirements concerning bacterial contamination at U.S. poultry slaughter plants, including the use of E. coli testing and Salmonella performance standards. This testimony is not relevant or material to the issue of whether Baytril is shown to be safe, and therefore this portion of Dr. Russell's testimony should be stricken from the evidentiary record.

Page 8, Line 5 through Page 9, Line 20 (all): This portion of the testimony addresses Salmonella and Listeria, not Campylobacter, and therefore is not relevant or material to the issue of the hearing. Therefore, Page 8, Line 5 through Page 9, Line 20 of Dr. Russell's testimony should be stricken as irrelevant and as immaterial.

Page 11, Line 3 through Page 12, Line 2 (all): The history of the HACCP program in the United States is not relevant or material to the issue of this hearing and therefore this portion of Dr. Russell's testimony should be stricken from the record.

Page 12, Lines 8-15 ("These companies...broiler processing."): This portion of Dr. Russell's testimony is not relevant or material to the issue for hearing. The ability to meet, and the cost of, USDA performance standards are not relevant or material to whether Baytril has been shown to be safe. Therefore, this portion of Dr. Russell's testimony should be stricken from the evidentiary record of the hearing.

Page 12, Line 21 through Page 13, Line 3 (all): None of the studies cited by Dr. Russell, B-1821, B-1822 and B-1823 involve studies of Campylobacter. Therefore these studies, and the conclusions drawn from these studies should be stricken from the record. Furthermore, since the studies do not involve Campylobacter, these studies do not support Dr. Russell's statement on Page 13, Lines 1-3 and therefore that statement should be stricken from the record because it is unsupported by the evidence. Furthermore, nothing within this portion of the testimony is relevant to the issue of the hearing, therefore, this portion of Dr. Russell's testimony should be stricken from the evidentiary record.

Page 13, Line 5 through Page 14, Line 4 ("Processing errors...during processing)." and Page 14, Lines 8-18 ("With extremely ...scores increase."): Because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of uniformity of carcass size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing.

Moreover, this testimony is speculative. Bayer ignores the fact that the mechanical process is optional: chickens and turkeys can both be eviscerated manually if the industry is willing to take the time and resources to do it and if consumers want poultry enough to pay for it, manually processed. Further, the prediction of increased pathogens is also speculative because it assumes the industry will not attempt to protect public health by reducing pathogens as much as possible in other ways. Therefore, this testimony should be stricken because it is so speculative as to be unreliable.

Moreover, this testimony is repetitive. Drs. Prucha, Tompkin, and Mr. Robach testify similarly. Therefore, for all these reasons, this portion of Dr. Russell's testimony should be stricken from the evidentiary record.

In addition, Page 13, Line 18 through Page 14, Line 4 (all), of Dr. Russell's testimony is not relevant to the issue of the hearing. The antibiotics used in the studies cited were not fluoroquinolone antibiotics and the time period for treatment was for a longer period of treatment duration than approved for fluoroquinolone use in poultry. Therefore, in addition to being irrelevant, the testimony is unsupported by the cited exhibits and therefore should be stricken on that ground as well. In addition, since Exhibits B-1832 and B-1827 do not support the statement on Page 14, Lines 2-4, they too should be stricken from the record.

Page 14, Line 19 through Page 15, Line 13 (all): The history of meat inspection, the creation of HACCP, and the inspection process are not relevant or material to the issue to be decided at hearing and therefore this portion of the testimony should be stricken as irrelevant and as immaterial.

Page 16, Line 10, through Page 17, Line 18 (all):. Because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of conformity to size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing.

This testimony is speculative. Bayer ignores the fact that the mechanical process is optional: chickens and turkeys can both be eviscerated manually if the industry is willing to take the time and resources to do it and if consumers want poultry enough to pay for it, manually processed. Further, the prediction of increased pathogens is also speculative because it assumes the industry will not attempt to protect public health by reducing pathogens as much as possible in other ways. Therefore, this testimony should be stricken because it is so speculative as to be unreliable.

Moreover, this testimony is repetitive. Drs. Prucha, Tompkin, and Mr. Robach testify similarly. Therefore, for all these reasons, this portion of Dr. Russell's testimony should be stricken from the evidentiary record.

Further, if this testimony is stricken on any ground, the exhibits cited in support of this testimony, B-1117, B-1825, B-1826, B-1829, B-1830, B-1831, and B-1836 should likewise be stricken from the evidentiary record of this hearing.

Page 17, Line 19 through Page 18, Line 2 (all): This testimony is not supported by the record. First, the cited exhibits do not have anything to do with feed withdrawal due to any disease, but rather from forced withdrawal of feed prior to slaughter. The first article, B-1829 addresses forced feed withdrawal prior to slaughter. The second article deals with feed patterns and food clearance in the broilers' digestive systems. Neither article can support the conclusory statement in the testimony. Therefore, Line 21 on Page 17 through Line 2 on Page 18, and Exhibit B-1836 and B-1827, should be stricken from the record of this hearing.

Page 18, Lines 3-5 (all): Because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of uniformity of carcass size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing. Therefore, this portion of Dr. Russell's testimony should be stricken from the evidentiary record.

Page 18, Lines 6-12 (all): This testimony should be stricken as immaterial. The potential lower body weight of poultry is not relevant or material to the issue of the hearing, as explained above. Further, the two studies cited, B-1827 and B-1832 are immaterial and should likewise be stricken.

Page 18, Line 13 through Page 19, Line 8 (all): This testimony, concerning two unnamed broiler operations, based on unpublished data by an unidentified researcher (although we assume it to be the witness) should be stricken because it is unsupported by the record and, without more information than is presented, is unreliable.

Page 19, Line 17 through Page 24, Line 17 (all) and Page 25, Line 4 through Page 26, Line 14 "This research...infection in humans", and Attachment 1 (B-1912 Attachment 1): The testimony presented is a description of research that Dr. Russell conducted that tests the relationship between pre-chiller microbial loadings and the disease conditions of the live birds coming into the slaughterhouse. Dr. Russell asserts that this testimony is relevant because it demonstrates that broilers that had air sacculitis and were treated with alternate therapies were underweight and less uniform. However, because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of conformity to size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing.

Moreover, this testimony is speculative. Bayer ignores the fact that the mechanical process is optional: chickens and turkeys can both be eviscerated manually if the industry is willing to take the time and resources to do it. Further, the prediction of increased pathogens is also speculative because it assumes the industry will not attempt to protect public health by reducing pathogens as much as possible in other ways. Therefore, this testimony should be stricken since it is so speculative as to be unreliable.

Further, if this testimony is stricken, the exhibits cited in support of this testimony, B-1014, B-1833, and B-557, as well as Attachment 1 to his testimony, should likewise be stricken from the evidentiary record of this hearing.

Page 26, Lines 15-17 ("The recent...air sacculitis"): The efficacy of Baytril is not relevant to the issue of the hearing. Therefore, this portion of the testimony should be stricken from the evidentiary record.

Page 26, Lines 17-22 ("My study...Campylobacter infections") and Attachments #3 and #4: This conclusory statement is based on Dr. Russell's earlier testimony subject to this motion. Therefore, it too is irrelevant and immaterial as well as speculative and should be stricken as such. If this testimony is stricken, CVM also believes that Attachments #3 and #4 to this testimony should be stricken for the same reasons.

Page 27, Line 1 through Page 30, Line 2 (all) and Attachments #3 and #4: This information should be stricken from the record on reliability grounds. The witness has failed to identify the companies whose records were reviewed, preventing verification. Therefore, this testimony is unreliable and should be stricken from the evidentiary record. For the same reasons, CVM believes that Attachments #3 and #4 to this testimony should be stricken from the evidentiary record. Further, the testimony is irrelevant and immaterial to the issue of the hearing, as well as speculative, for the reasons set out above (irrelevancy of cost factors; variables of the slaughter process; assumptions on what the industry will or will not do; etc.).

Page 30, Lines 7-10 ("It is my opinion...consumer."): This testimony should be stricken on reliability grounds. The witness is not an expert in economics and cannot offer an expert opinion on the cost of the removal of Baytril to the industry. Further, such testimony is

irrelevant and immaterial because financial issues are not related to, nor helpful in the determination of, the issue for hearing.

Page 30, Line 17 through Page 31, Line 1 ("I interviewed...problems."): This portion of the testimony should be stricken form the evidentiary record on relevancy grounds. The speed of the production line is mainly a financial concern and costs should not be taken into consideration in a new animal drug safety determination under the FDCA. Further, this statement should be stricken from the evidentiary record on reliability grounds because neither the plant manager or the plant has been identified, preventing verification.

Page 31, Lines 1-14 ("Someone at the...to date."): This portion of the testimony should be stricken because it is too speculative to be reliable and because the witness is not qualified to present testimony on costs. Further, the portion of the testimony that does deal with costs is irrelevant to a new animal drug safety determination under the FDCA.

Page 31, Line 15 through Page 33, Line 5 (all): These conclusions should be stricken from the Written Direct Testimony of Dr. Russell because they are irrelevant, immaterial and unreliable for the reasons set out above.

Attachment #2: CVM moves to strike this attachment to Dr. Russell's testimony because it is repetitive. The testimony itself covers the study presented in this attachment. Further, the arguments for striking portions of Dr. Russell's testimony, which are set out in this memorandum above, apply equally to this attachment. Therefore, the attachment should be stricken in its entirety. If the Administrative Law Judge finds that this attachment is not repetitive and does not strike it in its entirety, then CVM respectfully requests that the Administrative Law Judge strike those portions of this attachment that are irrelevant, immaterial or unreliable, based on the arguments presented above.

Peter Silley

The Center for Veterinary Medicine moves to strike the entire written direct testimony of Dr. Peter Silley, as it is merely a partial repetition (and should also be stricken because it is unreliable, being almost entirely free of supporting citation to reliable sources) of his undated Attachment 1. This repetition is most clearly seen in comparing his "Executive Summary" [Silley WDT page 5 through page 15, line 15] to his Attachment #1, pages 25-56. Dr. Silley's attachment bears two different page numbers on each page, but no line numbers on any page. References in this Motion to his attachment will rely on the bold-typed page number on the third line of the Docket and Attachment information at the lower right hand corner of each page of his attachment.

Alternatively, the Center moves to strike pages 25-56 of Dr. Silley's Attachment #1 as repetition of pages 5-15 of his written direct testimony.

If the entire testimony is not stricken, the Center moves to strike the specific portions identified below, for the reasons indicated after the specification.

Page 6, lines 4-7 (Paragraph 1.6) and Attachment, page 25 (Paragraph 1.6): This material should be stricken because it is repetitive of the testimony of Drs. Carnevale and DeGroot, see Carnevale WDT at Page 7, lines 1-16 and DeGroot WDT page 9, line 9 through page 12, line 18.

Page 6, lines 18-23 Paragraph on *C. upsaliensis*: This paragraph should be stricken as irrelevant and immaterial to the hearing issue, whether Baytril has been shown to be safe.

Page 7, lines 12-18 Paragraph that notes that mixtures of some bacteria "appear to be more common than was heretofore assumed...": This paragraph should be stricken because it is speculative and unreliable, as explicitly based on the appearance of something, compared to what (unspecified persons) heretofore assumed.

Page 8, lines 20-21 and page 27, paragraph 1.19 "There are factors other than the use of antibiotics within the production phase of poultry production that will contribute to the emergence of antibiotic resistant strains.": This statement should be stricken as the existence of other factors is irrelevant to the issue of this hearing. If Baytril is (or is not) shown to be safe, those other factors are immaterial.

Page 10, lines 1-4 and page 28, paragraph 1.24, beginning "Few authors detail isolation procedures used with regard to published work..." but citing no such work, nor any review concluding that: These statements should be stricken as unreliable as they are explicitly dependant upon a review of the studies relied upon for the statement, but do not provide a verifiable citation to enable the proposition to be evaluated.

Page 10, lines 5-6 and page 28, paragraph 1.25, "The use of antimicrobials in the isolation media has the opportunity to have a profound effect on MIC data.": This sentence should be stricken as misleading in that it suggests that one antimicrobial in a growth media would have a profound effect on MIC data for another antimicrobial agent.

Page 10, lines 7-9 and page 28, paragraph 1.26, "In *E. coli, hipA* and *hipQ* are selected for in the presence of a β-lactam antibiotic resulting in isolates with not only increased MICs to the β-lactam but also to quinolones. It is not known whether similar mechanisms exist in *Campylobacter* spp.": These sentences should be stricken as irrelevant and immaterial by their own terms, and as unreliable because they are without any apparent citation or connection to the issue for this hearing.

Page 10, lines 10-11 and page 28, paragraph 1.27, "Selection for multi drug efflux pumps could arise from use of antimicrobial selective agents.": This sentence should be stricken as unreliable because it is speculation, on its face.

Page 10, lines 18-19, and page 28, paragraph 1.30, "A link between β-lactam and fluoroquinolone resistance in *Streptococcus pneumoniae* has recently been suggested.": This sentence should be stricken because it is irrelevant and immaterial.

Page 11, lines 2-3 and page 28, paragraph 1.32, "An approved method for *Campylobacter* susceptibility testing for isolates of animal origin was not available until May 2002 when

NCCLS published M31-A2.": This sentence should be stricken as it is misleading, in that it suggests that NCCLS is the only standard-setting organization for *Campylobacter* testing, and that there can be no other approved methods for *Campylobacter* testing.

Page 13, lines 8-11 and page 30, paragraph 1.48, "Faecal concentrations following oral dosage of ciprofloxacin in humans suggest that *Campylobacter* spp...should in most cases be clinically susceptible....this would support...": These sentences should be stricken because they are unreliable, as speculation ("should in most cases...would support"). Additionally, they are unreliable because Dr. Silley is not a Medical Doctor and not qualified to state what would be clinically susceptible, and because the speculation about susceptibility is contradicted by the witness's own testimony, at page 49, first complete paragraph.

Page 16, lines 4-6, and page 54, subparagraph (e), declaring that "It is therefore not possible to isolate ..." and attribute a single strain as the disease causing strain, because samples support multiple species and strains of *Campylobacter*: These sentences should be stricken because they are inconsistent, and the second does not follow "therefore" from the first, in order to justify a statement that "It is therefore not possible".

Page 18, lines 11-15: These sentences repeat the contentions of Page 13, lines 8-11 and should be stricken as repetitive, and for the reasons set out for this passage as specified above.

Page 19, lines 3-9 where Dr. Silley makes an assumption about another witness's testimony and then constructs a lack of clarity from his own assumption: These sentences should be stricken for being unreliable, as based on the readers' unsupported assumption.

Page 21, lines 16-19 "Miché & Balandreau (2001) demonstrated that hypochlorite, routinely added to drinking water in poultry houses and used in chiller tanks, was responsible for an increase in the frequency of nalidixic acid-resistant mutants of *Burkholderia vietnamiensis*." This sentence should be stricken as irrelevant and misleading, if the reader thought that Dr. Silley's citation to the Miché & Balandreau (2001) paper signaled any reference in that paper to the use of hypochlorite in "drinking water in poultry houses and used in chiller tanks". That paper (later revealed to be B-983) describes the effect of hypochlorite as used as a surface sterilant on rice grains, and makes no mention of drinking water in poultry houses or chiller tanks. Dr. Silley's insert of the link to poultry houses can be read as a grammatical apposition, an extension of the meaning of hypochlorite. If the reader does not find this misleading, then all the rest of Dr. Silley's references must be read with this degree of caution in mind. In any event, the sentence should be stricken as irrelevant to the issue for this hearing, which does not involve the safety of nalidixic acid, nor the mutation or resistance-inducing capability of hypochlorite on *Burkholderia vietnamiensis* when used a surface sterilant on rice seed.

Pages 38-41, Section 3.2 "Possible Implications of Use of Antimicrobials in Isolation Media": this section should be stricken for the irrelevancy and speculative nature revealed in the section heading.

Page 41 section 3.3 titled in full: "Support for the" [sic]: this section should be stricken because it is misleading and unreliable, in that it purports to draw conclusions from an ongoing study that is not fully cited, and for which not even an abstract is cited to the record.

Pages 45-53 section 5, titled in full "Interpretation of the Data": This section should be stricken as irrelevant, and immaterial. A brief reading of these pages will demonstrate that the section is mainly disconnected summaries of papers and includes (at pp 47-48) a long series of not-even-allegedly-related suggestions about data quality for certain microbiological determinations, followed by 5 more pages of irrelevant ruminations, criticisms, and reviews of a variety of papers, without coherent relation to the issue for this hearing.

Pages 53-56 sections 6.1"Isolation methods" , 6.2 "Susceptibility Testing Methods" and 6.3 "Breakpoints" should all be stricken as unreliable testimony, in the absence of any proximate citation to reliable sources (there are no citations to any paper or authority in these three sections).

Anthony E. van den Bogaard

The Center moves to strike the following specified portions of the Written Direct Testimony of Dr. Anthony E. van den Bogaard for the reasons stated with each specification:

Page 4, line 20 through page 5, line 12, "In addition, Bayer has provided to me a list of references that were provided to CVM as part of the New Animal Drug Application (NADA) for enrofloxacin. This information, plus other literature available prior to the approval of enrofloxacin demonstrates that, at the time of approval of enrofloxacin in 1996, CVM was aware of data and information demonstrating (and had concluded) that: * * *.": This testimony should be stricken as unreliable and misleading, as it is intentionally constructed so as to convey an air of precision, but also so to lack any citation to the particular documents that Bayer provided to Dr. van den Bogaard that convinced him demonstrated these particular conclusions, or that CVM had made the alleged conclusions. So neither the Center, nor the Administrative Law Judge can find the particular quotes alleged to have been conclusions of the CVM, as learned by someone at Bayer, and conveyed to someone in Bayer, who not only conveyed some list of references to Dr. van den Bogaard, but convinced him as to the exact language of CVM's conclusions at that time. The marked contrast between the precision of the allegation and the total lack of a verifiable citation for this testimony makes it misleading, as well as unreliable.

Page 14, lines 15-16, "Thus FDA should have known that some resistance would develop even under the measures put in place.": This sentence should be stricken as unreliable speculation, in which the witness declares what FDA should have known, without reciting, let alone citing, all the information FDA had and was being told at the time.

Page 14, lines 18-19, "There is no new evidence that the use of enrofloxacin is now unsafe ...": this clause should be stricken as unreliable (and so sweeping as to defy the existence of things of which the witness is not aware, as better phrased in his preceding sentence). It is, in any event, irrelevant to the issue of this hearing: whether Baytril is shown to be safe. If the

inversion of the burden in the witness's statement was mere mistake, this sentence is unreliable. If it was intentional, then this sentence should be stricken as misleading as well, as it misphrases the issue for hearing.

Page 15, lines 10 – 12, "In this context, it should be noted that fluoroquinolone resistance...is not spread via plasmids to other genus and species." This sentence should be stricken as irrelevant and immaterial, because the human health problems caused by fluoroquinolone resistance from poultry are not dependant on being spread by plasmids. Because the conditional "via plasmids" phrase was inserted, this sentence could mislead the reader into thinking that Dr. van den Bogaard was challenging the spread of fluoroquinolone resistance to other species by means other than plasmids.

Page 15, lines 18-21, "In this respect, it should also be noted that the new macrolides such as azithromycin or clarithromycin are the drugs of first choice in the rare cases where campylobacteriosis need to be treated with antibiotics": This sentence should be stricken as unreliable medical testimony from a witness who has not been qualified as a medical doctor. Beyond that, this sentence is irrelevant because to whatever extent that fluoroquinolone-resistant campylobacter could represent a risk of treatment failure to humans, the risk is just as significant if the human patients are treated with Bayer's Ciprofloxacin, whether it is given as a first choice, or as a last hope.

Ronald Joseph Prucha

CVM moves to strike Dr. Prucha's testimony in its entirety. This testimony is repetitive and therefore, the entire testimony should be stricken from the evidentiary record. Similar testimony appears in Mr. Robach's and Drs. Russell's and Tompkins' testimony. The repetitiveness of these testimonies is evident from each witness' description of their own testimony as set out above.

Alternatively, CVM moves to strike several portions of Dr. Prucha's testimony. Most of the portions of Written Direct Testimony listed below are not relevant to the issue of the hearing. Dr. Prucha presents testimony on a variety of irrelevant issues, from the role of FSIS in addressing pathogens of meat products to the necessity of educating consumers to the dangers of improper food handling. Further, many portions of this testimony are repetitive and should be stricken from the record. The following provides more detail about why CVM believes specified portions of Dr. Prucha's testimony should be stricken from the evidentiary record.

Page 3, Lines 10 – 17 "Microbial food safety...human disease.": This hearing involves the safety of enrofloxacin under approved conditions for use in poultry. This portion of Dr. Prucha's testimony lists common foodborne pathogenic bacteria, and specifically discusses E. coli 0157:H7 as the only pathogen to be declared by FSIS to be an adulterant in raw meat and poultry. Whether any of these bacteria are considered to be an adulterant by FSIS has absolutely no bearing on the ultimate issue of this hearing. Therefore, the testimony contained on Page 3, Lines 10-17 of Dr. Prucha's testimony should be stricken from the evidentiary record as irrelevant.

Page 4, Lines 13-19 (all): This testimony addresses the responsibility of the consuming public and the food producing industries for controlling food borne illness. This testimony has nothing to do with the ultimate issue of the hearing, as set out by the Commissioner in the Notice of Hearing, and will not assist in a determination of the safety of Baytril. Therefore, this portion of Dr. Prucha's testimony should be stricken from the evidentiary record as irrelevant and/as immaterial.

Page 4, Line 20 through Page 6, Line 6 "HACCP...(Pierson and Corlett 1992; 182,187)": The HACCP system is not relevant or material to whether enrofloxacin is shown to be safe. Therefore, this portion of the testimony should be stricken as irrelevant. Further, Mr. Robach's and Drs. Russell's and Tompkins' testimony contains similar discussions about HACCP. Therefore this portion of the testimony is repetitive and should be stricken from the record.

Page 6, Lines 7-21 through Page 7, Lines 1-2 (all): Lines 7-17 of Page 6 of the testimony presented involves a description of the National Advisory Committee on Microbiological Criteria for Foods and its adoption of a HACCP document. Lines 18-21, of Page 6 through Lines 1-2 on Page 7 presents purported quotes from FDA about the HACCP system. However, none of the information presented in this part of the testimony is relevant to the issue at hearing and therefore should be stricken from the record on relevancy grounds. Furthermore, Lines 18-21 of Page 6 through Lines 1-2 of Page 7 should be stricken on reliability grounds. The document cited within this portion of the testimony indicates that FDA's comments pertain to the food establishment industries (i.e. restaurants) not the poultry production/slaughter industry. This portion of the testimony should be stricken because the source cited for the quotes provided do not support the testimony of this witness.

Page 7, Lines 3-15 (all): The testimony presented on Page 7, Lines 3-8 of Dr. Prucha's testimony involve a description of FSIS' responsibility and authority under the Federal Meat Inspection Act and the Poultry Products Inspection Act.[9] Neither statute, nor FSIS' responsibilities and authorities thereunder, are relevant or material to whether Baytril has been shown to be safe under the approved conditions of use in poultry under the standards set out in the FDCA. Therefore, the testimony contained on Page 7, Lines 3-15 of Dr. Prucha's testimony should be stricken as irrelevant and/or immaterial.

Page 8, Line 14 through Page 10, Line 28 (all): The control points of the HACCP process are not relevant nor material to the question of whether enrofloxacin has been shown to be safe. Therefore, this portion of the testimony should be stricken from the evidentiary record as irrelevant and/or immaterial.

Page 11, Lines 3-9 (all): The role and authority of FSIS inspectors is not relevant or material to the issue of whether enrofloxacin has been shown to be safe under the approved conditions of use for poultry. Therefore, this portion of the testimony should be stricken from the evidentiary record of this hearing as irrelevant and/or immaterial.

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[9] The scope of Poultry Products Inspection Act does not extend to regulation over the use of new animal drugs. Bell v. Goddard, 366 F.2d 177 (1966).

Page 11, Lines 11-21 "I have seen...is treated": Page 11, Lines 11-21 contain a recitation of findings from the research conducted by Dr. Scott Russell, one of Bayer's witnesses in this hearing. Dr. Russell's testimony covers this research in detail and therefore Page 11, Lines 11-21 of Dr Prucha's testimony should be stricken as repetitive. Further, Dr. Prucha has not testified that he has any independent knowledge of this study. Dr. Russell, who is already presenting testimony on this study, is more qualified to speak of his own research. Moreover, as argued elsewhere in this memorandum, CVM does not believe this study is relevant to whether enrofloxacin has been shown to be safe, and that conclusions drawn from the study are speculative at best. Therefore, this portion of the testimony should be stricken from the evidentiary record as irrelevant, repetitive and unreliable.

Page 12, Lines 1-17 (all): The testimony presented on Page 12, Lines 1-17 of Dr. Prucha's testimony involve a description of FSIS' responsibilities of administering the Poultry Products Inspection Act, and a statement that E. coli is the only meat or poultry product-borne pathogen to be considered an adulterant by USDA. None of this information is relevant to whether Baytril has been shown to be safe under the approved conditions of use in poultry under the standards set out in the FDCA, the statute governing approval and withdrawal of new animal drugs. Therefore, the testimony contained on Page 12, Lines 1-17 of Dr. Prucha's testimony should be stricken on relevancy grounds.

Page 12, Line 18 through Page 13, Line 20 (all) and Page 13, Line 22 through Page 14, Line 1 "If anything...process.": Once again, the testimony on Page 12, Line 18 through Page 13, Line 20 addresses the Poultry Products Inspection Act and its implementing regulations. Once again, none of this information is relevant to whether Baytril has been shown to be safe under the approved conditions of use in poultry under the standards set out in the FDCA. Therefore, the testimony contained on Page 12, Line 18 through Page 13, Line 20 of Dr. Prucha's testimony should be stricken on relevancy grounds. Further, it is irrelevant and immaterial to the issue of this hearing how USDA treats these pathogens. Whether or not USDA treats Campylobacter (or fluoroquinolone resistant Campylobacter) as an adulterant, or whether FSIS makes no distinction concerning antibiotic susceptibility when a positive pathogen sample is found, will not help determine the safety of enrofloxacin for use under the approved conditions of use in poultry. Therefore, in addition to the fact it is irrelevant to the issue of the hearing, it will also not be an aid to a determination of the issue of the hearing and therefore should also be stricken on materiality grounds.

Page 14, Lines 3-6 (all): Page 14, Lines 3-6 contain statements that the prevalence of susceptible Campylobacter far exceeds that of fluoroquinolone resistant Campylobacter in the poultry population. This statement is immaterial to the issue to be determined at the hearing. Therefore, Page 14, Lines 3-6 should be stricken from the record on materiality grounds.

Page 14, Lines 7-15 (all): The conclusions presented on Page 14, Lines 7-15 should be stricken on relevancy grounds. These conclusions are all based on Dr. Prucha's testimony, which is subject to this Motion to Strike. Therefore, if the Prucha testimony is stricken, there is no basis for these conclusions. Further, the conclusory statements themselves are irrelevant to the issue of the hearing and should be stricken from the record on relevancy grounds.

Page 17, from the beginning of the chart through the end of the Page: The chart presented on Page 17 is not relevant or material to the issue of the hearing. The chart does not purport to address foodborne illness caused specifically by Campylobacter or fluoroquinolone-resistant Campylobacter. Therefore, CVM moves that this chart be stricken from the record as irrelevant and immaterial.

Page 18 through Page 21 (with the exception of four lines on Page 19): This information should be stricken. With the exception of the four lines addressing Campylobacter on Page 19, this information is not relevant to the issue of the hearing. Further, the information is not reliable. There is no indication of where this information comes from, no citation within the testimony itself that identifies the origin of this information and therefore no other reason to believe that this information is reliable. Further, the information is not part of the testimony – for example, it is not incorporated into the testimony and appears after the certification and signature of the witness. Therefore CVM respectfully moves to strike Pages 18-21 as irrelevant and unreliable.

Robert Bruce Tompkin

CVM moves to strike Dr. Tompkin's testimony in its entirety. This testimony is repetitive and therefore, the entire testimony should be stricken from the evidentiary record. Similar testimony appears in Drs. Prucha's and Russell's and Mr. Robach's testimony. The repetitiveness of these testimonies is evident from each witness' description of their own testimony as set out above, at the beginning of the section on Mr. Robach's testimony.

Alternatively, CVM moves to strike several portions of Dr. Tompkin's testimony. Most of the portions of Written Direct Testimony listed below are not relevant to the issue of the hearing. Dr. Tompkin presents testimony on a variety of irrelevant issues from the description of the International Commission on Microbiological Specifications for Foods, to the goals of a Food Safety Strategic Plan adopted by the Council on Food Safety.

Further, many portions of this testimony is repetitive and should be stricken from the record. The following provides more detail about why CVM believes these portions of Dr. Tompkin's testimony should be stricken from the evidentiary record.

Page 3, Line 10 through Page 5, Line 22 ("A significant...Assistant Secretary for Health."): The purpose and membership of the International Commission on Microbiological Specifications in Foods (ICMSF) and the National Advisory Committee on Microbiological Specifications for Foods (NACMSF) are not relevant to the issue for hearing as set out by the Commission in the Notice of Hearing. Therefore, this portion of Dr. Tompkin's testimony should be stricken from the evidentiary record of this hearing.

Page 6, Line 18 through Page 7, Line 2 (all); and Page 7, Lines 6-21 (all): Information on Salmonella, Escherichia coli (E. coli)[10], and Listeria monocytogenes is not relevant or material to the issue of the hearing. Therefore, this portion of the testimony should be stricken from the evidentiary record as irrelevant and/or immaterial.

Page 8, Lines 19-21(all): Greater awareness of, and consumer concern about, food borne disease is not relevant nor material to the issue of hearing, and should, therefore, be stricken from the evidentiary record.

Page 15, Line 17 through Page 16, Line 3 ("It has been...of FoodNet."): Dr. Tompkin has not been presented as an expert in epidemiology, and therefore, is not qualified to offer his expert opinion on what the epidemiological data shows. Therefore, this portion of the testimony should be stricken as unreliable.

Page 16, Lines 8-20 (all): Testimony on HACCP and results of HACCP are not relevant or material to the issue of this hearing. Therefore, this portion of the testimony should be stricken from the evidentiary record of the hearing.

Page 16, Line 21 through Page 27, Line 22 ("Federal food safety....required by regulation."): This portion of Dr. Tompkin's testimony is irrelevant and immaterial to the issue of the hearing. This testimony presents information on how many plants implement HACCP; the role of FSIS, FDA, EPA, CDC, USDA and NMFS; the Food Safety Strategic Plan; food safety management control measures; and, the HACCP programs. None of these topics are relevant to the issue of the hearing and none will assist the Administrative Law Judge in reaching a determination in this hearing. Therefore, this entire portion of Dr. Tompkin's testimony should be stricken as irrelevant and/or immaterial.

Page 28, Lines 3-9 ("USDA does not...are so important."): Whether USDA considers certain microbes to be adulterants is not relevant or material to the issue of the hearing. Therefore, this testimony should be stricken from the record of this hearing.

Page 28, Line 10 through Page 29, Line 18 (all): USDA's HACCP program and farm to table food strategy are not relevant or material to the issue of this hearing and, therefore, this portion of the Dr. Tompkin's testimony should be stricken from the evidentiary record.

Page 30, Line 19 through Page 34, Line 13 (all): This portion of Dr. Tompkin's testimony is irrelevant and immaterial to the issue for hearing. FSIS' Salmonella standards, requirements for E. coli testing as a microbial indicator for fecal contamination, the use of Salmonella as a target organism for FSIS' performance standard requirements, and reasons why FSIS has not set a performance standard based on Campylobacter, are not relevant or material to the issue for hearing, nor will it assist the Administrative Law Judge in reaching a determination in this hearing. Therefore, this portion of Dr. Tompkin's testimony should be stricken as irrelevant and as immaterial.

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[10] Although the target organism for the use of Baytril in poultry is E. coli causing respiratory disease in the poultry, this portion of Dr. Tompkin's testimony appears to present E. coli as an enteric pathogen in humans, and is therefore irrelevant and immaterial to the issue for hearing.

Page 34, Line 14 through Page 37, Line 16 (all): FSIS' request to NACMCF for input on microbiologic performance standards is not relevant nor material to the issue of this hearing and should be stricken from the evidentiary record.

Page 38, Line 3 through bottom of the chart (all): Prevalence data, and reduction in prevalence, of Salmonella is not relevant or material to the issue of whether enrofloxacin is safe, and, therefore, this portion of the testimony should be stricken from the evidentiary record as irrelevant and as immaterial.

Page 38, Line 12 through Page 42, Line 12 (all): To the extent this testimony addresses Salmonella instead of Campylobacter, it is not relevant or material to the issue of the hearing. Further, a *microbial* risk assessment is not relevant or material to the issue of the hearing. Because this testimony focuses on a microbial risk assessment, and not an antimicrobial resistance risk assessment, this testimony should be stricken from the evidentiary record as irrelevant and as immaterial.

Page 46, Lines 7-13 (all): This portion of the testimony is not relevant or material to the issue of the hearing. A *microbial* risk assessment is not relevant or material to the issue of the hearing. Because this testimony focuses on a microbial risk assessment, and not an antimicrobial resistance risk assessment, this testimony should be stricken from the evidentiary record as irrelevant and as immaterial.

Page 51, Line 11 through Page 55, Line 2 ("Variation in the size...of food borne disease."): The testimony presented by this portion of Dr. Tompkin's testimony is a description of research that another witness, Dr. Russell, conducted that tests the relationship between pre-chiller microbial loadings and the disease conditions of the live birds coming into the slaughterhouse, and conclusions based on other research from Dr. Russell on the size of diseased carcasses and level of fecal contamination on carcasses. However, because the poultry slaughter industry can choose (among many variables to change) to slow the kill line or manually process flocks or individual chickens, the real factor being argued by Bayer is that the lack of uniformity of carcass size/weight is the financial cost to the industry, not the drug safety issue of this hearing. Financial costs are not relevant to the ultimate issue of this hearing.

This testimony is also speculative. Bayer ignores the fact that the mechanical process is optional: chickens and turkeys can both be eviscerated manually if the industry is willing to take the time and resources to do it and if consumers want poultry enough to pay for it, manually processed. Further, the prediction of increased pathogens is also speculative because it assumes the industry will not attempt to protect public health by reducing pathogens as much as possible in other ways. Therefore, this testimony should be stricken because it is so speculative as to be unreliable.

Moreover, this testimony is repetitive. Dr. Russell, the researcher in the studies described by Dr. Tompkin, testifies similarly. If any testimony regarding these studies is allowed to remain on the record (and CVM has set out reasons why such testimony should not be entered elsewhere in this Memorandum), Dr. Russell, not Dr. Tompkin, would be more qualified to offer such

testimony. For all of these reasons, this portion of Dr. Tompkin's testimony should be stricken from the evidentiary record as irrelevant, immaterial, and unreliable.

Page 55, Line 3 through Page 56, Page 2 (all): Dr. Tompkin's opinion that Federal policy should be coordinated is not relevant or material to the issue of the hearing. This portion of the testimony is not related to the issue of whether Baytril has been shown to safe, nor can it help the Administrative Law Judge in a determination in this matter. Likewise, a microbial risk assessment used to develop an estimate of the public health impact of campylobacteriosis is not relevant or material to an estimate of fluoroquinolone-resistant campylobacteriosis.

Page 56, Lines 3-18 (all): Dr. Tompkin is not an expert in poultry purchasing and therefore he is not qualified to present an opinion on this matter. Therefore, this portion of Dr. Tompkin's testimony should be stricken as unreliable.

Page 57, Lines 16-21 (all): The public health goal of reducing Campylobacteriosis is not relevant nor material to the issue of whether Baytril has been shown to be safe and, therefore, should be stricken from the evidentiary record.

Page 58, Lines 1-8 (all): The conclusions reached by Dr. Tompkin about reducing the prevalence of Campylobacter and salmonella on raw poultry, and preventing carcass contamination are not material to the issue of the hearing and should be stricken from the record.

Page 58, Lines 11-14 (all): Usefulness of E. coli and Salmonella as indicators is not relevant or material to the issue of drug safety as set out in the Notice of Hearing. Therefore, this portion of Dr. Tompkin's testimony should be stricken as irrelevant and immaterial.

Page 58, Lines 15-16 (all): Dr. Tompkin has not been presented as an expert in epidemiology and is not qualified to reach this conclusion. Therefore, this portion of the testimony should be stricken as unreliable.

Page 58, Line 17 through Page 59, Line 2 (all): The conclusions presented in this portion of Dr. Tompkin's testimony are based on his earlier testimony subject to this Motion to Strike including Dr. Tompkin's conclusions based on Dr. Russell's testimony. Because CVM believes the underlying testimony is irrelevant, immaterial, unreliable and repetitive, CVM likewise believes this testimony should be stricken on these grounds.

Page 59, Lines 3-8 (all): Again, Dr. Tompkin is not an expert in poultry purchasing and therefore he is not qualified to present an opinion on this matter. Therefore, this portion of Dr. Tompkin's testimony should be stricken as unreliable.

Roger A. Feldman

The Center moves to strike the following designated portions of the Written Direct Testimony of Dr. Feldman for the reasons specified with each designated portion.

Page 40, Lines 5-16 ("Dr. Tony Cox., a Bayer expert witness... said that...monthly incidence can be observed." This portion of Dr. Feldman's testimony is explicitly based solely on

a repetition of the testimony of Dr. Cox. Therefore, this portion of the testimony should be stricken as repetitive.

Richard A. Carnevale

The Center moves to strike the following designated portions of the Written Direct Testimony of Dr. Carnevale for the reasons specified with each designated portion. [Note: In Dr. Carnevale's testimony, the text lines generally do not match up with the line numbers on the left sides of the pages and the spacing of the text lines is greater than the spacing of the line numbers. Because of this mismatch, the following system will be used to identify text lines in Dr. Carnevale's testimony: (1) where a text line happens to match up with a line number, that line number will be used to identify the text line; and (2) where a text line does not match up with a line number, the line number immediately preceding the text line will be used to identify the text line.]

Attachment 3: In Attachment 3, Dr. Carnevale purports to have transcribed portions of statements, allegedly made by CVM witness Dr. Frederick Angulo, that were recorded with a tape recorder by Dr. Carnevale for his personal use. Attachment 3 is so patently unreliable as to be worthless. As evident from Dr. Carnevale's transcript of the recording he made, several "answers" and portions of answers, as well as some "questions," were deemed "inaudible." Moreover, as Dr. Carnevale testifies, the quoted lines in Attachment 3 are "some excerpts from the recording," which excerpts he says are themselves excerpts of statements made, i.e., Attachment 3 is an ad hoc excerpt of an excerpt. There are no means to verify the accuracy of the recording or to what extent the material transcribed, as well as the recording itself, has been excerpted. For all these reasons, Attachment 3 should be stricken from the evidentiary record of this hearing as unreliable.

Attachment 1; and

Attachment 2; and

Page 4, Line 26 through Page 7, Line 16 ("The deficiencies .... populations."); and

Page 9, Line 8 through Line 24 (all); and

Page 10, Line 3 through Page 15, Line 19 (all); and

Page 16, Line 11 through Page 19, Line 25 (all): In these parts of his testimony, Dr. Carnevale testifies about the animal and human NARMS programs and bases his testimony on Attachment 1 (a report prepared for the Animal Health Institute by Michael E. Ginevan) and Attachment 2 (a review by Michael E. Ginevan, which presents information similar to Attachment 1). Dr. Carnevale's testimony throughout these pages covers: (a) changes in isolation sources in animal NARMS (Page 5, Line 5 through Page 6, Line 27); (b) techniques of, and changes in, isolation methodology in animal NARMS (Page 7, Line 1 through Line 16; Page 9, Line 8 through Line 24); (c) whether sampling methods in human NARMS bias results toward

higher resistance (Page 11, Line 1 through Page 12, Line 14); (d) whether human NARMS campylobacter program is population-based (Page 12, Line 16 through Page 15, Line 14); (e) whether protocols in human NARMS are being followed (Page 16, Line 11 through Page 18, Line 9); (f) whether human NARMS addresses foreign travel, prior treatment risk factors (Page 18, Line 11 through Line 22); and (g) whether isolation methodology in human NARMS is standardized (Page 18, Line 24 through Page 19, Line 4). This portion of Dr. Carnevale's testimony listed in (a) to (g) is repetitive of Dr. DeGroot's testimony on the following pages (listed in (a) to (g), respectively): (a) DeGroot, Page 6, Line 6 through Page 9, Line 8; (b) DeGroot, Page 9, Line 9 through Page 12, Line 18; (c) DeGroot, Page 20, Line 10 through Page 24, Line 12; (d) DeGroot, Page 17, Line 22 through Page 19, Line 15; (e) DeGroot, Page 30, Line 1 through Page 34, Line 7; (f) DeGroot, Page 19, Line 16 through Page 20, Line 9 and Page 25, Line 16 through Line 23; and (g) DeGroot, Page 28, Line 1 through Page 29, Line 5. Therefore, this portion of Dr. Carnevale's testimony (including Attachments 1 and 2) should be stricken from the evidentiary record of this hearing as repetitive.

Further, portions of testimony within the preceding paragraph should be stricken for the following additional reasons:

Page 9, Line 8 through Line 24 (all): In these lines, Dr. Carnevale testifies to the skewing of mixed cultures towards higher resistance levels and states, "This has occurred in the NARMS program." This portion of his testimony is unreliable in that he provides no citation to support his assertion and does not appear to have any independent knowledge of this information based on his stated experience and expertise. Therefore, this portion of Dr. Carnevale's testimony should also be stricken from the evidentiary record of this hearing as unreliable.

Page 11, Line 14 through Line 21 ("At the 2002 ... Attachment 3."); and

Page 13, Line 2 through Line 9 ("Indeed, even ... prevalence."); and

Page 14, Line 19 through Line 24 ("At the 2002 .... meaningful."); and

Page 14, Line 27 through Page 15, Line 2 ("Using ... meaningful."): In these parts of his testimony, Dr. Carnevale paraphrases portions of Attachment 3, which is an ad hoc excerpt (transcript) of an excerpt (tape recording). For all the reasons at the beginning of this section on Dr. Carnevale's testimony that describe the patent unreliability of Attachment 3, this portion of Dr. Carnevale's testimony should also be stricken from the evidentiary record of this hearing as unreliable.

Page 13, Line 10 through Line 27 ("During .... sample.'"); and

Page 14, Line 24 through Line 27; ("He stated .... approach.'"); and

Page 19, Line 21 through Line 25 ("When ... trend.'"): In these parts of his testimony, Dr. Carnevale is quoting from Attachment 3. For all the reasons at the beginning of this section on Dr. Carnevale's testimony that describe the patent unreliability of Attachment 3, this portion of

Dr. Carnevale's testimony should also be stricken from the evidentiary record of this hearing as unreliable.

Page 15, Line 2 through Line 10 ("In essence .... analysis."): In these lines, Dr. Carnevale gives a summary and conclusions based on Attachment 3. For all the reasons at the beginning of this section on Dr. Carnevale's testimony that describe the patent unreliability of Attachment 3, this portion of Dr. Carnevale's testimony should also be stricken from the evidentiary record of this hearing as unreliable.

Page 18, Line 18 through Line 19 ("Even Dr. Angulo acknowledged at the 2002 NARMS Annual Scientific Meeting that the program was only intended to direct research and was never intended to be used for regulatory purposes."): This portion of Dr. Carnevale's testimony is unreliable because it is not supported by any citation to verify, or even suggest, that Dr. Angulo ever made such a statement. Therefore, this portion of Dr. Carnevale's testimony should also be stricken from the evidentiary record of this hearing as unreliable.

Page 21, Line 16 through Line 19 ("FSIS do [sic] not consider bacteria resistant to one or more antimicrobials to be added substances. FSIS does not consider Campylobacter exhibiting in vitro resistance to fluoroquinolones to be 'added substances' due to the use of an antibiotic."): This portion of Dr. Carnevale's testimony is irrelevant to the issue of the hearing. The United States Department of Agriculture Food Safety and Inspection Service's (FSIS) definition of "added substance" has no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 21, Line 19 through Line 27 ("The use of a fluoroquinolone such as Baytril does not cause the occurrence of fluoroquinolone resistance in the Campylobacter population. Fluoroquinolone resistance in Campylobacter exists due to a spontaneously occurring genetic event in a population of Campylobacter, which occurs at a certain frequency regardless of the presence or absence of fluoroquinolones. The fluoroquinolone doesn't cause the resistance; the resistance simply exists in nature. The fact that this spontaneous genetic mutation may or may not confer a survival advantage in the local environment of the Campylobacter is irrelevant to the question of whether the resistance is caused due to the use of a fluoroquinolone such as Baytril."); and

Page 22, Line 2 through Line 5 ("The Campylobacter exist independent of the use of Baytril (i.e. Baytril did not create them), and the presence or absence of resistance in the population of Campylobacter exists independent of the use of Baytril (i.e. Baytril did not cause the genetic mutation that leads to fluoroquinolone resistance)."): These parts of Dr. Carnevale's testimony are irrelevant and immaterial to the issue of the hearing. In fact, Dr. Carnevale's focus on the mutation event borders on illogical. The relevant and material concern for purposes of this hearing is that, once the mutation event occurs, the resistance, in the presence of Baytril, provides a selective advantage in Campylobacter. For this reason, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant and immaterial.

Page 22, Line 6 through Page 23, Line 17 (all): In these pages, Dr. Carnevale assumes that FSIS believes that fluoroquinolone resistant Campylobacter are "added substances" under USDA's Poultry Products Inspection Act (PPIA) and hypothesizes that, if FSIS believed that those "added substances" were poisonous or deleterious, then FSIS, under the PPIA, would have to condemn the poultry products as adulterated. This portion of Dr. Carnevale's testimony is unreliable and irrelevant to the issue of the hearing. Dr. Carnevale assumes a condition (FSIS's interpretation of "added substances") that is irrelevant to the issue of this hearing and testifies to a hypothetical scenario of his own creation, which is pure speculation and unreliable testimony. Moreover, whether FSIS would consider substances to be poisonous or whether FSIS would condemn poultry products under Dr. Carnevale's hypothetical has no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Page 23, Line 18 through Page 24, Line 20 (all): In these pages, Dr. Carnevale testifies to safe food handling labels pursuant to FSIS regulations. This portion of Dr. Carnevale's testimony is irrelevant to the issue of the hearing. FSIS regulation of food handling labels has no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 24, Line 22 through Page 25, Line 21 (all): In these pages, Dr. Carnevale testifies to Hazard Analysis and Critical Control Point (HACCP) regulation under USDA. This portion of Dr. Carnevale's testimony is irrelevant to the issue of the hearing. USDA's HACCP regulation has no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Attachment 4; and

Page 25, Line 22 through Page 26, Line 14 (all): In these parts of his testimony, Dr. Carnevale testifies to the opinion of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) on whether FSIS should adopt a Campylobacter "performance standard." Attachment 4 purports to be a May 1999 NACMCF report on that same issue. This portion of Dr. Carnevale's testimony is irrelevant to the issue of the hearing. Whether FSIS should adopt a "performance standard" and NACMCF's opinion on whether FSIS should adopt a "performance standard" have no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony (including Attachment 4) should be stricken from the evidentiary record of this hearing as irrelevant.

Page 26, Line 16 through Page 27, Line 1 (all): In these pages, Dr. Carnevale testifies that FSIS "does not have the scientific information to set meaningful health related standards for safety of Campylobacter on raw chicken carcasses." This portion of Dr. Carnevale's testimony is irrelevant to the issue of the hearing. Dr. Carnevale's assertion that FSIS lacks certain scientific

information to formulate health related standards has no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 27, Line 2 through Line 8 ("The .... resistance."); and
Page 27, Line 12 through Page 28, Line 4 ("Because the .... reasonable?"); and

Page 28, Line 9 through Line 26 (all): In these parts of his testimony, Dr. Carnevale draws on his unreliable and irrelevant testimony found in pages 22 and 26 and hypothesizes, if Baytril is no longer shown to be safe, that FSIS must consider raw poultry containing ciprofloxacin resistant Campylobacter to be adulterated under USDA's statutes and also that FDA has scientific information that NACMCF does not have. In this portion of his testimony, Dr. Carnevale uses his hypothetical to draw conclusions that are irrelevant and immaterial to the issue of this hearing. FSIS's determination of adulteration under USDA statutes and NACMCF's scope of scientific information have no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant and immaterial.

Page 29, Line 1 through Line 16 (all): In these lines, Dr. Carnevale testifies to an assumption that he alleges was made by CVM in CVM's risk assessment; i.e., that "even 1 colony-forming unit (CFU) has the ability to colonize the human intestinal tract and cause disease." This portion of his testimony is unreliable. CVM uses the prevalence of fluoroquinolone resistant Campylobacter on carcasses; when fluoroquinolone resistant Campylobacter are detected, it would be highly unlikely that there is but 1 CFU on the carcass. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 29, Line 17 through Page 30, Line 12 (all): In these pages, Dr. Carnevale testifies that, if Baytril is removed from the market and flocks cannot be treated for air sacculitis, there will be an increase in Campylobacter contamination on raw poultry. Dr. Carnevale also seems to allude to a shift in the incidence of campylobacteriosis as a result of unsuccessfully treated air sacculitis in chickens. This portion of his testimony is unreliable. Dr. Carnevale's statement regarding air sacculitis treatment failure and its effect on Campylobacter levels in poultry is pure speculation. Moreover, Dr. Carnevale's allusion to a change in campylobacteriosis incidence assumes that the poultry industry will not take any measures to reduce Campylobacter contamination on raw poultry in those flocks with "untreatable" air sacculitis. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 31, Line 11 through Line 13 ("and, in so ... inspection."): In these lines, Dr. Carnevale testifies that CVM's action "is clearly at odds with the Food Safety and Inspection Service." This portion of Dr. Carnevale's testimony is unreliable and irrelevant to the issue of the hearing. Dr. Carnevale's assertion is pure speculation and has no bearing on whether Baytril has been shown to be safe under the standards set forth in the Federal Food, Drug, and Cosmetic

Act. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Page 31, Line 15 through Page 34, Line 17 (all): In these pages, Dr. Carnevale testifies that CVM's risk assessment does not follow the microbial risk assessment as outlined by FDA's Center for Food Safety and Applied Nutrition (CFSAN). This portion of Dr. Carnevale's testimony fails to recognize that there is a distinction between the commodities that the Centers regulate and that risk assessments are tailored accordingly. Dr. Carnevale's comparison of CVM's risk assessment with CFSAN's model, which is a microbial risk assessment, rather than an antimicrobial resistance risk assessment is irrelevant and immaterial to the issue of this hearing. Moreover, this portion of Dr. Carnevale's testimony is repetitive of the testimonies of Dr. Louis Anthony Cox (Page 7, Line 1 through Line 3; Attachment 1, Page 1 through Page 3) and Dr. Charles Haas (Page 8, Line 5 through Page 9, Line 5 (including Table)). For all these reasons, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as irrelevant, immaterial, and repetitive.

Further portions of testimony within the preceding paragraph should be stricken for the following additional reasons:

Page 34, Line 10 through Line 17 ("CVM .... incorporated."): In these lines, Dr. Carnevale testifies to CVM's alleged process of gathering and incorporating comments on its risk assessment. This portion of his testimony, which consists of pure speculation, is unreliable and irrelevant to the issue of this hearing. For these reasons, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Page 34, Line 19 through Page 35, Line 10 (all): Dr. Carnevale entitles this section of his testimony, "Process Not Transparent," and alleges that AHI was rebuffed in its attempts to engage in dialogues with CVM about the law and about risk assessments. This portion of his testimony, which consists of self-serving remarks, is unreliable and irrelevant to the issue of this hearing. For these reasons, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Page 35, Line 11 through Line 26 (all): Dr. Carnevale entitles this section of his testimony, "Failure to Provide Evidence to Bayer." Dr. Carnevale alleges that Bayer was rebuffed in its attempts to engage in dialogues with CVM about the soon-to-be-issued NOOH. This portion of his testimony, which casts gratuitous aspersions on behalf of Bayer against CVM, is unreliable and irrelevant to the issue of this hearing. For these reasons, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Attachment 5: and

Attachment 6; and

Page 36, Line 1 through Page 37, Line 2 (all): Dr. Carnevale entitles this section of his testimony, "Questionable CDC Activities," and alleges that CDC: (a) did not respond in a timely fashion to FOIA requests made by Bayer (Bayer's FOIA requests and selected CDC responses are in Attachment 5); and (b) gave an activist group preferential access to data (purports to be in Attachment 6). This portion of his testimony is unreliable and irrelevant to the issue of this hearing. For these reasons, this portion of Dr. Carnevale's testimony (including Attachments 5 and 6) should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Page 37, Line 3 through Page 38, Line 27 (all): This portion of Dr. Carnevale's testimony is also included in the section he calls "Questionable CDC Activities," and here he alleges that CVM witness Dr. Angulo's written direct testimony filed in this hearing contradicts Dr. Angulo's 2002 NARMS Annual Scientific Meeting presentation. His allegations against Dr. Angulo are based on Attachment 3, which, as described at the beginning of this section on Dr. Carnevale's testimony, is patently unreliable. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 39, Line 5 through Line 12 (all): In these lines, Dr. Carnevale attempts to show a discrepancy in CVM witness Dr. Tollefson's testimony. This portion of Dr. Carnevale's testimony is unreliable. To prove his assertion, Dr. Carnevale provides a two-sentence summary that paraphrases a portion of the 1994 Advisory Committee meeting minutes. Dr. Carnevale's quoted text of Dr. Tollefson's testimony, however, does not match the context of Dr. Carnevale's two-sentence summary of the Advisory Committee meeting. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 39, Line 23 through Line 24 (all): In these lines, Dr. Carnevale paraphrases from Attachment 3, which, as described at the beginning of this section on Dr. Carnevale's testimony, is patently unreliable. Therefore, this portion of Dr. Carnevale's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Attachment 7; and

Page 41, Line 26 through Page 42, Line 10 (all): In these parts of his testimony, Dr. Carnevale testifies to the "SENTRY program" and the "JONES Group" report in Attachment 7. This portion of his testimony is unreliable. Attachment 7 is unreadable (i.e., with the exception of a few words, the text of the attachment cannot be read with the naked eye) and this unreadable version appears to be the only version that is in the evidentiary record. Therefore, this portion of Dr. Carnevale's testimony (including Attachment 7) should be stricken from the evidentiary record of this hearing as unreliable.

Bradley D. DeGroot

The Center moves to strike the following designated portions of the Written Direct Testimony of Dr. DeGroot for the reasons specified with each designated portion.

Attachment 4; and

Page 9, Line 15 through Page 12, Line 18 (all): In these parts of his testimony, Dr. DeGroot testifies that the animal NARMS laboratory methods between 1998 – 2001 raised the probability of classifying a specimen as resistant. This portion of his testimony is unreliable because it is internally inconsistent with his testimony that states, "Moreover, changes in microbiological methods reveal that all previous estimates of ciprofloxacin resistance underestimated the true prevalence [Tollefson Testimony G-1478]" (emphasis added) on page 14, line 19 through line 20. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Further, portions of testimony within the preceding paragraph should be stricken for the following additional reasons:

Attachment 4; and

Page 10, Line 17 through Page 12, Line 2 (all): In these parts of his testimony, Dr. DeGroot testifies to a report, attached to his testimony as Attachment 4, that was prepared for the U.S. Poultry & Egg Association by Dr. Margie Lee. This portion of his testimony is unreliable because it facially misrepresents Dr. Lee's report. The following paragraph, quoted from Dr. DeGroot's testimony, compares Dr. DeGroot's testimony, by strike-out and double-underline format, with Dr. Lee's report in Attachment 4. As can been seen, the quoted portion of Dr. Lee's report in Dr. DeGroot's testimony is an inaccurate representation of the text of Dr. Lee's report in Attachment 4; therefore, this portion of Dr. DeGroot's testimony (including Attachment 4) should also be stricken from the evidentiary record of this hearing as unreliable for this reason.

> "Dr. Lee posits that 'Campylobacter resistance data currently collected by the NARMS study, and used by ~~CVM~~ FDA in its consideration of the fluoroquinolone approval issue, may be skewed because the participating laboratories often use these selective procedures when detecting Campylobacter. The participating laboratories are free to use the ~~media~~ medium which works best for them meaning that there is no ~~mandatory~~ standardization among the labs. Many of the labs ~~have elected to~~ use media with ~~antimicrobials~~ antibiotics ~~to suppress the growth of other bacteria~~ because it makes ~~the~~ isolation of Campylobacter from much easier ~~to isolate~~. If our hypothesis is correct, the frequency of occurrence of resistant Campylobacter may be overestimated and this erroneous data ~~information~~ may lead the FDA to conclude that certain veterinary ~~antimicrobials~~ antibiotics have a greater impact on human health ~~than~~ that they actually ~~have~~ do.' Dr. Lee concludes that 'The results of NARMS may erroneously indicate that resistant ~~Campylobacter~~ campylobacters are ~~more~~ common ~~than they really are~~ and that ~~antimicrobial~~ antibiotic usage in poultry production is selecting for ~~those~~ resistant strains.'"

Page 17, Line 23 through Page 18, Line 17 ("Data collected for the Human NARMS program do not represent the general United States population .... Human NARMS makes no such adjustment, nor has it collected or provided any data to allow for such an adjustment."): In these pages, Dr. DeGroot testifies that, because of "selection biases," the human NARMS sample

population does not represent the general population of the United States. This portion of his testimony is unreliable and immaterial to the issue of the hearing. Dr. DeGroot confuses the issue of bias with the issue of generalizability. The "bias" Dr. DeGroot raises is not bias but rather a standard issue of generalizability that occurs in most public health surveillance programs, which are typically based on existing clinical diagnostic laboratory data. Moreover, even assuming the truthfulness of Dr. DeGroot's statements (despite his unconventional terminology) referenced here, the data from the human NARMS public health surveillance program would not be "invalid and useless," as Dr. DeGroot asserts. For all these reasons, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable and immaterial.

Page 19, Line 16 through Page 20, Line 9 (all): In these pages, Dr. DeGroot testifies that the human NARMS program fails to determine any deviation of the human NARMS sample population from the general United States population on various ciprofloxacin resistance risk factors. For the same reasons described above, this portion of his testimony is unreliable and immaterial to the issue of the hearing. The issue Dr. DeGroot raises is not one of "selection" or "sampling" bias but rather a standard issue of generalizability that occurs in most public health surveillance programs. Public health surveillance systems are not designed to collect data on risk factors but rather serve as a platform for additional analytic epidemiology studies such as the Campylobacter case control study conducted by CDC. Moreover, even assuming the truthfulness of Dr. DeGroot's statements referenced here, the data from the human NARMS public health surveillance program would not be "invalid and useless," as Dr. DeGroot asserts. For all these reasons, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable and immaterial.

Page 25, Line 7 through Line 15 ("Inclusion .... risk [Martin et al., 1987]."); and

Page 26, Line 1 through Line 12 (all): In these parts of his testimony, Dr. DeGroot testifies that the human NARMS sample population does not represent the general population of the United States because human NARMS is based on ill people seeking medical care. For the same reasons described above, this portion of his testimony is unreliable and immaterial to the issue of the hearing. Dr. DeGroot confuses the issue of bias with the issue of generalizability. The "bias" Dr. DeGroot raises is not bias but rather a standard issue of generalizability that occurs in most public health surveillance programs, which are typically based on existing clinical diagnostic laboratory data. Ill people seeking medical care is the population of interest in human NARMS. Moreover, even assuming the truthfulness of Dr. DeGroot's statements referenced here, the data from the human NARMS public health surveillance program would not be "invalid and useless," as Dr. DeGroot asserts. For all these reasons, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable and immaterial.

Page 30, Line 1 through Page 33, Line 2 (all); and

Page 33, Line 18 through Page 34, Line 7 (all): In these parts of his testimony, Dr. DeGroot testifies to the numbers of samples submitted to human NARMS and concludes there is "potential data corruption" in human NARMS. This portion of his testimony is unreliable and

immaterial. This testimony, which is based on Dr. DeGroot's version of the data set, is pure speculation. Without more information (and none has been offered by Dr. DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. Moreover, Dr. DeGroot makes an inappropriate and unwarranted assumption that, simply because a sample was submitted, the sample was necessarily susceptibility tested or was part of a final dataset used for analysis. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable and immaterial.

Further, portions of testimony within the preceding paragraph should be stricken for the following additional reasons:

Page 30 , Line 23 through Line 24 ("Figure 1 plots isolate submission data provided from CDC to Bayer Corporation."): In these lines, Dr. DeGroot testifies to Bayer's receipt of data from CDC. This portion of his testimony is unreliable because: (1) Dr. DeGroot does not have personal knowledge of any data transfer from CDC to Bayer; (2) this testimony is beyond the scope of Dr. DeGroot's expertise; and (3) this testimony is not the proper subject of expert opinion. Therefore, this portion of Dr. DeGroot's testimony should also be stricken from the evidentiary record of this hearing as unreliable.

Page 34, Line 8 through Page 45, Line 3 (all): In these pages, Dr. DeGroot testifies that CDC's data set does not comply with FDA regulations set forth at 21 C.F.R. Part 11. This portion of Dr. DeGroot's testimony is irrelevant because 21 C.F.R. Part 11 does not apply to CDC's data set. Moreover, this portion of Dr. DeGroot's testimony is pure speculation and therefore unreliable because the analysis and conclusions presented here are based on Dr. DeGroot's version of the data set. Without more information (and none has been offered by Dr. DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as irrelevant and unreliable.

Further, portions of testimony within the preceding paragraph should be stricken for the following additional reasons:

Page 34, Line 11 through Line 12 ("Bayer received data sets underlying the Human NARMS published reports via a FOIA request by its counsel and provided the data sets for me to review."); and

Page 38, Line 21 through Line 23 ("However, it is impossible to reconstruct Campylobacter counts presented in all yearly reports currently available (1997, 1998, 1999, 2000) using data provided by the CDC in response to FOIA requests."); and

Page 39, Line 11 through Line 13 ("However, using that for an inclusion criterion results in huge discrepancies between the Annual Reports and data provided by the CDC in response to FOIA requests."); and

Page 40, Line 3 through Line 6 ("Internal discrepancies within reports, discrepancies between Human NARMS data provided by the CDC in response to FOIA requests, and NARMS Annual Reports (supposedly based on them), demonstrate that the CDC has not successfully preserved the Human NARMS data for subsequent analysis and scrutiny."); and

Page 40, Line 7 through Line 9 ("Dr. Angulo's testimony [G-1452] provides further indication that data used by the CDC for its analyses are not the data it provided to Bayer Corporation's counsel in response to FOIA requests."); and

Page 40, Line 13 through Line 16 ("However, in data provided to Bayer by the CDC, age is available for only 890 observations and age and sex together are available for only 887 observations. The CDC data sent to satisfy the FOIA requests were not the same data used by Dr. Angulo and his analysts."); and

Page 41, Line10 through Line 12 ("The Human NARMS data provided to Bayer Corporation have been edited and the CDC has made no provision to audit Human NARMS data."); and

Page 42, Line 11 through Line 13 ("Again, no user identifiers or references to electronic signatures are associated with any of the Human NARMS data provided by the CDC in response to FOIA requests."):

In these parts of his testimony, Dr. DeGroot testifies to Bayer's (or Bayer's counsel's) receipt of data from CDC, at times referring to FOIA requests. This portion of his testimony is unreliable because: (1) Dr. DeGroot does not have personal knowledge of any data transfer from CDC to Bayer (or Bayer's counsel); (2) this testimony is beyond the scope of Dr. DeGroot's expertise; and (3) this testimony is not the proper subject of expert opinion. Therefore, this portion of Dr. DeGroot's testimony should also be stricken from the evidentiary record of this hearing as unreliable for these reasons.

Page 45, Line 7 (all); and

Page 48, Line 1 through Page 50, Line 5 (all); and

Page 52, Line 10 through Line 12 ("That means ... violation."); and

Page 52, Line 14 through Page 53, Line 4 ("Due to the ... and year."); and

Page 54 Line 13 through Line 16 ("However ... not provide."): In these parts of his testimony, Dr. DeGroot testifies to alleged data discrepancies in human NARMS data. This portion of his testimony is unreliable. This testimony, which is based on Dr. DeGroot's version of the data set, is pure speculation. Without more information (and none has been offered by Dr.

DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 60, Line 18 through Page 61, Line 2 ("While the CDC ... are not."): In these pages, Dr. DeGroot testifies to Bayer's counsel's receipt of data from CDC pursuant to FOIA requests. This portion of his testimony is unreliable because: (1) Dr. DeGroot does not have personal knowledge of any data transfer from CDC to Bayer's counsel; (2) this testimony is beyond the scope of Dr. DeGroot's expertise; and (3) this testimony is not the proper subject of expert opinion. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 62, Line 1 through Page 63, Line 16 (all): In these pages, Dr. DeGroot testifies to declining incidence of campylobacter in humans. This portion of his testimony is immaterial to the issue of the hearing. The existence and extent of, and reasons for, any decline in campylobacter infections in humans will not aid in determining whether Baytril has been shown to be safe based on antimicrobial resistance concerns. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as immaterial.

Page 65, Line 4 through Line 6 (all): In these lines, Dr. DeGroot testifies that selection media raise MICs for campylobacter, which is related to his testimony that the animal NARMS laboratory methods between 1998 – 2001 raised the probability of classifying a specimen as resistant (page 9, line 15 through page 12, line 18). For the same reasons described previously, this portion of his testimony is unreliable because it is internally inconsistent with his testimony that states, "Moreover, changes in microbiological methods reveal that all previous estimates of ciprofloxacin resistance underestimated the true prevalence [Tollefson Testimony G-1478]" (emphasis added) on page 14, line 19 through line 20. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 66, Line 17 through Line 20 ("Furthermore, data provided by the CDC in response to FOIA requests indicate that the agency has been incapable of mustering the discipline necessary to reliably and securely manage the detailed data necessary to perform these adjustments even if it attempted to do so."): This portion of his testimony is unreliable because: (1) Dr. DeGroot does not have personal knowledge of any data transfer from CDC in response to FOIA requests; (2) this testimony is beyond the scope of Dr. DeGroot's expertise; and (3) this testimony is not the proper subject of expert opinion. Moreover, this testimony, which is based on Dr. DeGroot's version of the data set, is pure speculation. Without more information (and none has been offered by Dr. DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 66, Line 21 through Page 67, Line 2 (all): In these pages, Dr. DeGroot testifies to alleged data discrepancies. This portion of his testimony is unreliable. This testimony, which is based on Dr. DeGroot's version of the data set, is pure speculation. Without more information (and none has been offered by Dr. DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 67, Line 3 through Line 11 (all): In these lines, Dr. DeGroot testifies to CDC's response to FOIA requests, alleged data discrepancies, and CDC's compliance with FDA regulations set forth at 21 C.F.R. Part 11. This testimony, which deals with FOIA requests, is unreliable because: (1) Dr. DeGroot does not have personal knowledge of any data transfer from CDC in response to FOIA requests; (2) this testimony is beyond the scope of Dr. DeGroot's expertise; and (3) this testimony is not the proper subject of expert opinion. This testimony, which deals with alleged data discrepancies, is also unreliable because it is based on Dr. DeGroot's version of the data set and is pure speculation. Without more information (and none has been offered by Dr. DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. This testimony, which deals with FDA's regulations at 21 C.F.R. Part 11, is also irrelevant because 21 C.F.R. Part 11 does not apply to CDC's data set. For all these reasons, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable and irrelevant.

Page 67, Line 17 through Page 68, Line 4 ("These levels ... chance."): In these pages, Dr. DeGroot testifies to alleged data discrepancies. This portion of his testimony is unreliable. This testimony, which is based on Dr. DeGroot's version of the data set, is pure speculation. Without more information (and none has been offered by Dr. DeGroot), there is no way to know whether any data manipulation or data transfer between software packages that was done by Dr. DeGroot, or by anyone on his behalf, corrupted the data set and is responsible for any data discrepancies alleged by Dr. DeGroot. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 68, Line 15 through Line 21 (all): In these lines, Dr. DeGroot testifies to declining incidence of campylobacter in humans. This portion of his testimony is immaterial to the issue of the hearing. The existence and extent of, and reasons for, any decline in campylobacter infections in humans will not aid in determining whether Baytril has been shown to be safe based on antimicrobial resistance concerns. Therefore, this portion of Dr. DeGroot's testimony should be stricken from the evidentiary record of this hearing as immaterial.

Gregory A. Burkhart

The Center moves to strike the following designated portions of the Written Direct Testimony of Dr. Burkhart for the reasons specified with each designated portion.

Page 2, Line 42 through Line 44 ("1. The regulatory ... small."): In these lines, Dr. Burkhart testifies to the standard under which the regulatory decision to withdraw Baytril should be made. This portion of Dr. Burkhart's testimony is unreliable in that it is beyond the scope of permissible expert testimony. The standard for this regulatory decision is a matter of law and not subject to expert opinion. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 3, Line 12 through Line 14 ("However ... poultry."): In these lines, Dr. Burkhart's testimony addresses whether there is "significant morbidity" attributable to enrofloxacin use in poultry. This portion of his testimony is irrelevant to the issue of this hearing. Bayer previously attempted to reformulate the hearing issues to include a finding of significant morbidity attributable to poultry; Bayer's motion was denied. Whether humans suffer significant morbidity attributable to enrofloxacin use in poultry is not determinative of whether fluoroquinolone-resistant Campylobacter in poultry contribute to fluoroquinolone-resistant infections in humans (hearing issue A.2., NOH) or whether fluoroquinolone-resistant Campylobacter infections in humans have the potential to adversely affect human health (hearing issue A.3., NOH). Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 3, Line 18 through Line 20 ("Hence ... incidence rate."): In these lines, Dr. Burkhart testifies that there is no evidence that withdrawing Baytril would decrease the Campylobacter incidence rate. This portion of his testimony is irrelevant to the issue of this hearing. Whether the Campylobacter incidence rate would decrease after Baytril is withdrawn is not determinative of whether Baytril has been shown to be safe based on antimicrobial resistance concerns. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 4, Line 4 through Line 9 (all): In these lines, Dr. Burkhart testifies that CVM has not considered that fluoroquinolone-resistant Campylobacter can come from other potential sources besides poultry. This portion of his testimony is irrelevant to the issue of this hearing. Whether poultry is the only source of fluoroquinolone-resistant Campylobacter is not determinative of whether fluoroquinolone-resistant Campylobacter in poultry contribute to fluoroquinolone-resistant infections in humans. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 4, Line 19 through Line 20 ("Given ... benefit."): In these lines, Dr. Burkhart testifies to the standard under which the regulatory decision to withdraw Baytril should be made. This portion of Dr. Burkhart's testimony is unreliable in that it is beyond the scope of permissible expert testimony. The standard for this regulatory decision is a matter of law and not subject to expert opinion. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 4, Line 26 through Line 28 ("12. ... humans."): In these lines, Dr. Burkhart's testimony addresses whether there is "significant morbidity" attributable to enrofloxacin use in poultry. As stated above, this portion of his testimony is irrelevant to the issue of this hearing. Bayer previously attempted to reformulate the hearing issues to include a finding of significant

morbidity attributable to poultry; Bayer's motion was denied. Whether humans suffer significant morbidity attributable to enrofloxacin use in poultry is not determinative of whether fluoroquinolone-resistant Campylobacter in poultry contribute to fluoroquinolone-resistant infections in humans (hearing issue A.2., NOH) or whether fluoroquinolone-resistant Campylobacter infections in humans have the potential to adversely affect human health (hearing issue A.3., NOH). Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 7, Line 4 through Line 8 (all); and

Page 7, Line 13 through Line 16 ("Hence ... good."); and

Page 7, Line 18 through Line 25 (all); and

Page 7, Line 30 through Line 32 ("However ... action."): In these lines, Dr. Burkhart testifies to the standard under which the regulatory decision to withdraw Baytril should be made. This portion of Dr. Burkhart's testimony is unreliable in that it is beyond the scope of permissible expert testimony. The standard for this regulatory decision is a matter of law and not subject to expert opinion. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 9, Line 26 through Line 32 ("this conclusion ... Campylobacter."): In these lines, Dr. Burkhart testifies that CVM has not considered that fluoroquinolone-resistant Campylobacter can come from other potential sources besides poultry. This portion of his testimony is irrelevant to the issue of this hearing. Whether poultry is the only source of fluoroquinolone-resistant Campylobacter is not determinative of whether fluoroquinolone-resistant Campylobacter in poultry contribute to fluoroquinolone-resistant infections in humans. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 11, Line 4 through Line 8 ("I ... burden."): In these lines, Dr. Burkhart states that his testimony is based on whether there is "significant morbidity" attributable to enrofloxacin use in poultry. As stated above, this portion of his testimony is irrelevant to the issue of this hearing. Bayer previously attempted to reformulate the hearing issues to include a finding of significant morbidity attributable to poultry; Bayer's motion was denied. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.[11]

Page 11, Line 8 through Line 10 ("Obviously ... humans."): In these lines, Dr. Burkhart testifies to the standard under which the regulatory decision to withdraw Baytril should be made.

[11] Dr. Burkhart states: "I focused my review of this issue around the question of whether FQ use (mostly enrofloxacin) in poultry production in the US could be a 'significant' cause of domestically acquired FQ resistant Campylobacter." Considering that the issue on which Dr. Burkhart formulated his review is not part of the hearing issue, this one-sentence statement alone calls into question the relevance of Dr. Burkhart's entire testimony. On this basis, CVM moves to strike Dr. Burkhart's testimony in it entirety. In the alternative, CVM moves to strike portions of Dr. Burkhart's testimony as listed in the text of this motion.

This portion of Dr. Burkhart's testimony is unreliable in that it is beyond the scope of permissible expert testimony. The standard for this regulatory decision is a matter of law and not subject to expert opinion. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 15, Line 10 through Line 14 ("Presumably ... disease."): In these lines, Dr. Burkhart testifies that a review of exposure reservoirs should include potential sources besides poultry. This portion of his testimony is irrelevant to the issue of this hearing. Whether poultry is the only source of fluoroquinolone-resistant Campylobacter is not determinative of whether fluoroquinolone-resistant Campylobacter in poultry contribute to fluoroquinolone-resistant infections in humans. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 16, Line 4 through Line 11 ("According ... dataset."); and

Page 16, Line 13 through Line 14 ("Bayer's ... re-enter the data"): This portion of his testimony is unreliable because: (1) Dr. Burkhart does not have personal knowledge of any data transfer to Bayer (or Bayer's counsel) pursuant to FOIA; (2) this testimony is beyond the scope of Dr. Burkhart's expertise; and (3) this testimony is not the proper subject of expert opinion. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable for these reasons.

Page 17, Line 29 through Line 44 (all): This portion of his testimony is unreliable because Dr. Burkhart does not have personal knowledge of a "personal communication between Bayer and [CVM witness Dr. Kirk] Smith" and therefore cannot testify to his opinions regarding that communication. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable.

Page 24, Line 5 through Line 9 ("I .... oversight."); and

Page 42, Line 9 through Line 11 ("To ... questionnaire."); and

Page 43, Line 12 through Line 13 ("Bayer ... CDC."): This portion of his testimony is unreliable because: (1) Dr. Burkhart does not have personal knowledge of any data transfer to Bayer (or Bayer's counsel) pursuant to FOIA; (2) this testimony is beyond the scope of Dr. Burkhart's expertise; and (3) this testimony is not the proper subject of expert opinion. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as unreliable for these reasons.

Page 47, Line 9 through Line 16 (all); and

Page 48, Line 6 through Line 8 ("Whether ... unknown;"): In these lines, Dr. Burkhart testifies that a review of exposure reservoirs should include potential sources besides poultry and that there may be other ways besides enrofloxacin to contaminate poultry with resistant Campylobacter. This portion of his testimony is irrelevant to the issue of this hearing. Whether poultry is the only source of fluoroquinolone-resistant Campylobacter is not determinative of

whether fluoroquinolone-resistant Campylobacter in poultry contribute to fluoroquinolone-resistant infections in humans (hearing issue A.2., NOH); whether poultry can become contaminated with resistant Campylobacter in more ways than one is not determinative of whether enrofloxacin in poultry acts as a selection pressure resulting in the emergence in poultry of fluoroquinolone-resistant Campylobacter (hearing issue A.1., NOH). Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 48, Line 14 through Line 16 ("Determining ... complex."); and

Page 48, Line 36 through Line 38 ("The agency .... believe."): In these lines, Dr. Burkhart's testimony addresses whether there is "significant morbidity" attributable to enrofloxacin use in poultry. As stated above, this portion of his testimony is irrelevant to the issue of this hearing. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 50, Line 24 through Line 35 (all): In these lines, Dr. Burkhart testifies that a review of exposure reservoirs should include potential sources besides poultry and that there may be other ways besides enrofloxacin to contaminate poultry with resistant Campylobacter. As stated above, this portion of his testimony is irrelevant to the issue of this hearing. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this hearing as irrelevant.

Page 51, Line 2 through Line 5 (all): In these lines, Dr. Burkhart concludes that there is insufficient evidence to conclude that enrofloxacin in poultry is "causing significant morbidity to humans." As stated above, this portion of his testimony is irrelevant to the issue of this hearing. Therefore, this portion of Dr. Burkhart's testimony should be stricken from the evidentiary record of this

For the reasons set out above, the Center for Veterinary Medicine's Motion to Strike Written Direct Testimony and Exhibits should be granted.

Respectfully submitted,

Nadine Steinberg

Robert M. Spiller, Jr.

Claudia Zuckerman
Counsel for the Center for Veterinary Medicine

UNITED STATES OF AMERICA
BEFORE THE FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of:	FDA DOCKET: 00N-1571
	DATE: _____, 2003
Enrofloxacin for Poultry: Withdrawal of Approval of Bayer Corporation's New Animal Drug Application (NADA) 140-828 (Baytril)	

ORDER

By Motion filed January 27, 2003, the Center for Veterinary Medicine ("CVM") requests that certain portions of Bayer and AHI Written Direct Testimony be stricken from the evidentiary record of this hearing. A review of the Center's Motion and Memorandum in Support thereof shows that several portions of Bayer and AHI testimony are irrelevant to the issue of the hearing, immaterial to determination of the issue of the hearing, repetitive, and/or unreliable. Therefore, CVM's Motion is HEREBY GRANTED. [*In the alternative:* Therefore, CVM's Motion is HEREBY GRANTED with respect to those portions of the testimony marked and attached to this Order.]

DATED this the ____ day of _____, 2003.

_____
Daniel J. Davidson
Administrative Law Judge

Enrofloxacin Hearing
Docket No: 00N-1571

CERTIFICATE OF SERVICE

I hereby certify that an original and one copy of the foregoing Center for Veterinary Medicine's Motion to Strike and its accompanying Memorandum in Support was hand delivered this 27th day of January, 2003, to:

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, MD 20852

I also certify that a copy of the pleading and memorandum has been hand delivered and e-mailed, this 27th day of January, 2003, to:

The Office of the Administrative Law Judge
Food and Drug Administration
Room 9-57, HF-3
5600 Fishers Lane
Rockville, MD 20857

I also certify that a copy pleading and memorandum was e-mailed and deposited in First Class U.S. mail, this 27th day of January, 2003, addressed to:

Robert B. Nicholas
McDermott, Will & Emery
600 13th Street, NW
Washington, DC 20005

Kent D. McClure
Animal Health Institute
1325 G Street, NW, Suite 700
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Dated: 27 JAN 03

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