

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

In the Matter of:

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

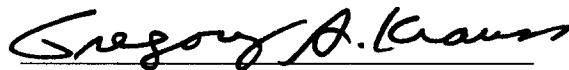
**Date: June 6, 2003**

0574 '03 JUN -6 P4:32

**RESPONDENT BAYER CORPORATION'S PROPOSED  
CORRECTIONS IN THE TRANSCRIPT OF ORAL TESTIMONY**

Pursuant to 21 CFR § 12.98(d) and Administrative Law Judge Davidson's Order dated May 9, 2003, Respondent Bayer Corporation hereby proposes corrections in the transcript of oral testimony as delineated on the attached "errata" sheets for each cross-examination witness. Each of the proposed corrections is for the purpose of correcting transcription errors. A proposed Order is attached.

Respectfully submitted,



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*Counsel for Bayer*

**CERTIFICATE OF SERVICE**

I hereby certify that an original and one copy of Respondent Bayer Corporation's Proposed Corrections in the Transcript of Oral Testimony was hand-delivered this 6<sup>th</sup> day of June, 2003 to:

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

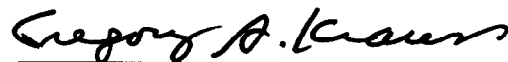
I also certify that a copy of the foregoing Proposed Corrections in the Transcript of Oral Testimony was e-mailed this 6<sup>th</sup> day of June, 2003 to:

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 of the foregoing Proposed Corrections in the Transcript of Oral Testimony was e-mailed and mailed via first-class mail, postage pre-paid, 6<sup>th</sup> day of June, 2003 to:

Nadine Steinberg  
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Rockville, MD 20857

Kent D. McClure  
Animal Health Institute  
1325 G Street, N.W, Suite 700  
Washington, D.C. 20005



Gregory A. Krauss  
*Counsel for Bayer*

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: April 28, 2003

WITNESS: Linda Tollefson

| <b>Page</b> | <b>Line</b> | <b>As Transcribed</b> | <b>Change To</b>   |
|-------------|-------------|-----------------------|--------------------|
| 27          | 19          | Cerofloxacin          | Sarafloxacin       |
| 28          | 15          | fluoroquinolones;     | fluoroquinolones”; |
| 36          | 7           | Greg,                 | Gregg,             |
| 52          | 10          | TOPES                 | Tauxe's            |
| 55          | 4           | of ruse               | for use            |
| 55          | 6           | Freedman              | Friedman           |
| 56          | 19          | CVM BOSE              | CVM/Vose           |
| 57          | 1           | CVM BOSE              | CVM/Vose           |
| 61          | 2           | Dr. Freedman          | Dr. Friedman       |
| 61          | 22          | this come             | this comes         |
| 62          | 5           | “8 Chicken            | . Ate chicken      |
| 63          | 6           | Freedman              | Friedman           |
| 64          | 14          | Freedman              | Friedman           |
| 66          | 22          | Freedman              | Friedman           |
| 67          | 17          | Freedman's            | Friedman's         |
| 70          | 13          | Homberg               | Holmberg           |
| 70          | 14          | Taket                 | Tacket             |
| 70          | 14          | Conan Talkes          | Cohen and Tauxe    |
| 70          | 14          | Bivey                 | Bibi               |
| 71          | 1           | Homberg               | Holmberg           |
| 71          | 10          | Taket                 | Tacket             |
| 71          | 20          | Conan Talkes          | Cohen and Tauxe    |
| 72          | 2           | Bivey                 | Bibi               |
| 75          | 11          | bed                   | be                 |
| 82          | 4           | lori                  | lari               |
| 94          | 13          | Minnick's             | Minnich's          |
| 97          | 3           | D-                    | B-                 |
| 100         | 1           | understanding         | understand         |
| 107         | 9           | from2000              | from 2000          |
| 108         | 8           | laundry               | monitoring         |
| 120         | 5           | non-typoid            | non-typhoid        |
| 120         | 8           | typing                | typhi              |
| 120         | 9           | non-typing            | non-typhi          |
| 120         | 13          | non-typing            | non-typhi          |
| 121         | 8           | One week              | One per week       |

|     |    |                |                |
|-----|----|----------------|----------------|
| 134 | 12 | Which          | Would          |
| 137 | 9  | thank          | to             |
| 137 | 22 | the            | that           |
| 140 | 18 | founded        | rounded        |
| 153 | 13 | no             | not            |
| 154 | 8  | Glysson        | Glisson        |
| 154 | 19 | Glysson's      | Glisson's      |
| 154 | 21 | Glysson's      | Glisson's      |
| 155 | 8  | Glysson's      | Glisson's      |
| 155 | 12 | Glysson's      | Glisson's      |
| 157 | 4  | Glysson        | Glisson        |
| 157 | 12 | ADUCA          | AMDUCA         |
| 159 | 9  | ADUCA          | AMDUCA         |
| 162 | 21 | ops            | authors        |
| 165 | 15 | Dr. Freedman   | Dr. Friedman   |
| 166 | 14 | Dr. Freedman   | Dr. Friedman   |
| 168 | 1  | Freedman       | Friedman       |
| 170 | 22 | Guilliam-Barre | Guillain-Barre |
| 171 | 2  | lead           | Mead           |
| 171 | 11 | lead           | Mead           |
| 182 | 1  | Guilliam-Barre | Guillain-Barre |
| 182 | 4  | Guilliam-Barre | Guillain-Barre |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: April 29, 2003

WITNESS: Robert Walker

| Page | Line | As Transcribed                | Change To                        |
|------|------|-------------------------------|----------------------------------|
| 188  | 12   | CVC                           | CDC                              |
| 188  | 14   | turnover                      | Tenover                          |
| 189  | 4    | proto-formula,                | protocol                         |
| 189  | 11   | CVC                           | CDC                              |
| 203  | 1    | free agents                   | reagents                         |
| 204  | 1    | micro-organisms               | microorganisms                   |
| 204  | 12   | micro-organisms               | microorganisms                   |
| 205  | 14   | micro-organism                | microorganism                    |
| 207  | 15   | Amacrolyte                    | macrolide                        |
| 210  | 19   | gastral enteritis             | gastroenteritis                  |
| 210  | 19   | and                           | an                               |
| 210  | 22   | And is what's                 | And it is what's                 |
| 217  | 9    | am I offered it?              | am I off of it?                  |
| 217  | 12   | Am I offered it?              | Am I off of it?                  |
| 222  | 9    | CVC                           | CDC                              |
| 222  | 10   | CVC                           | CDC                              |
| 236  | 5    | enterobacteriosis,            | Enterobacteriaceae               |
| 238  | 13   | gastro-enteritis              | gastroenteritis                  |
| 238  | 18   | pharmaco-kinetic              | pharmaco-kinetics                |
| 243  | 20   | whether that antimicrobial is | whether that an antimicrobial is |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: April 30, 2003

WITNESS: Frederick Angulo

| <b>Page</b> | <b>Line</b> | <b>As Transcribed</b>         | <b>Change To</b>                        |
|-------------|-------------|-------------------------------|---|
| 267         | 10          | attachment.                   | attachments.                            |
| 268         | 16          | jejune                        | jejuni                                  |
| 269         | 22          | offer                         | author                                  |
| 271         | 22          | till                          | until                                   |
| 272         | 2           | till                          | until                                   |
| 279         | 11          | date versus                   | data versus                             |
| 279         | 11          | date which                    | data which                              |
| 285         | 1           | apriority                     | a priori                                |
| 289         | 15          | fluoroquinolone Campylobacter | fluoroquinolone resistant Campylobacter |
| 293         | 16          | grahms                        | gram                                    |
| 294         | 2           | Chicatoxin                    | shiga toxin                             |
| 294         | 5           | Chagilla                      | Shigella                                |
| 294         | 17          | Chagilla                      | Shigella                                |
| 296         | 16          | Campyl                        | Campylobacter                           |
| 306         | 4           | Hard Net                      | Hardnett                                |
| 306         | 16          | site                          | cite                                    |
| 309         | 1           | HardNet                       | Hardnett                                |
| 310         | 3           | Hard Net                      | Hardnett                                |
| 322         | 7           | call                          | all                                     |
| 322         | 8           | venting                       | vetting                                 |
| 338         | 1           | or E. coli                    | or coli                                 |
| 344         | 19          | grahms                        | grams                                   |
| 345         | 12          | juni                          | jejuni                                  |
| 345         | 17          | to juni                       | jejuni                                  |
| 345         | 18          | coli so we                    | coli we                                 |
| 346         | 4           | isolate                       | isolates                                |
| 348         | 16          | milligrams                    | micrograms                              |
| 349         | 1           | resistant                     | resistance                              |
| 351         | 21          | or                            | for                                     |
| 353         | 11          | had an effective              | had ineffective                         |
| 360         | 3           | aggression                    | regression                              |
| 362         | 12          | is approximation              | is an approximation                     |
| 374         | 22          | juni                          | jejuni                                  |
| 395         | 13          | 1, 028                        | 1,028                                   |

|     |    |   |                     |
|-----|----|---|---------------------|
| 395 | 15 | was89   | was 89              |
| 399 | 9  | as  | is                  |
| 404 | 10 | controlled                                    | control             |
| 414 | 20 | Alteri  | poultry             |
| 431 | 20 | MR. NICHOLAS                                  | MR. SPILLER         |
| 433 | 1  | 899   | A-99                |
| 448 | 17 | medium  | median              |
| 449 | 22 | resistance                                    | resistant           |
| 450 | 15 | -- whether you know whether<br>you controlled | -- Smith controlled |
| 461 | 2  | apriority                                     | a priori            |
| 462 | 10 | apriority                                     | a priori            |
| 462 | 12 | apriority                                     | a priori            |
| 463 | 5  | apriority                                     | a priori            |

## ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: May 1, 2003

WITNESS: Kirk Smith

| Page | Line  | As Transcribed                | Change To                         |
|------|-------|-------------------------------|-----------------------------------|
| 483  | 7     | of the corporation.           | of the Bayer Corporation.         |
| 484  | 3     | norms                         | NARMS                             |
| 484  | 7     | scan.                         | scheme.                           |
| 488  | 19    | conducting cross examination. | conducting the cross-examination. |
| 491  | 21    | jurist?                       | reviewer?                         |
| 492  | 12    | review                        | reviewer                          |
| 494  | 6     | former                        | formal                            |
| 494  | 18    | methods analytical            | methods and analytical            |
| 494  | 20    | that was you                  | that you                          |
| 494  | 21    | all of those defined          | all of those been defined         |
| 497  | 4     | Embry,                        | Emery,                            |
| 498  | 5-6   | what information he got       | what information the witness got  |
| 498  | 6     | he                            | they                              |
| 503  | 2     | Pyddic, Gunn,                 | Piddock, Gaunt,                   |
| 503  | 3     | Thruolphal,                   | Threlfall,                        |
| 503  | 4     | Thruolphal                    | Threlfall                         |
| 504  | 5     | Pro crit                      | purpose                           |
| 505  | 11    | there prospective as          | this prospective, as              |
| 505  | 12    | got control                   | got a control                     |
| 505  | 16    | there                         | it                                |
| 507  | 11    | using nalidixic               | using a nalidixic                 |
| 508  | 1     | genes.                        | genus.                            |
| 508  | 2     | genes?                        | genus?                            |
| 513  | 8     | with                          | were                              |
| 516  | 19    | TCR                           | PCR                               |
| 521  | 5     | flore-typing                  | fla typing                        |
| 521  | 14    | great.                        | correct.                          |
| 523  | 11    | to                            | as                                |
| 524  | 14-15 | sources in poultry            | sources in particular poultry     |
| 530  | 19    | forms                         | subtypes                          |
| 536  | 2     | flaw                          | fla                               |
| 536  | 5     | flaw-typing                   | fla typing                        |
| 536  | 8     | Nachompkin                    | Nachampkin                        |
| 536  | 10    | following in the              | following the                     |
| 536  | 11    | Nachompkin                    | Nachampkin                        |



|     |    |                           |                           |
|-----|----|---------------------------|---------------------------|
| 536 | 15 | flaw                      | fla                       |
| 536 | 20 | Flaw                      | Fla                       |
| 536 | 20 | F-L-A-W.                  | F-L-A.                    |
| 536 | 21 | Flaw                      | Fla                       |
| 538 | 7  | But wouldn't you consider | But you wouldn't consider |
| 538 | 20 | detection                 | detected                  |
| 547 | 7  | we can die of variables   | we can divide variables   |
| 547 | 9  | flawed                    | fla                       |
| 556 | 6  | FLAG                      | FLA                       |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: May 2, 2003

WITNESS: Heidi Kassenborg

| <b>Page</b> | <b>Line</b> | <b>As Transcribed</b> | <b>Change To</b>    |
|-------------|-------------|-----------------------|---------------------|
| 567         | 17          | packaging             | pathogens           |
| 572         | 2           | CBM's                 | CVM's               |
| 573         | 5           | draft                 | direct              |
| 578         | 13          | infectious diseases   | Infectious Diseases |
| 579         | 1           | chagella              | Shigella            |
| 589         | 6           | read                  | lead                |
| 589         | 18          | here do you           | here is do you      |
| 590         | 6           | purposes today        | purposes of today   |
| 597         | 2           | final                 | find a              |
| 605         | 10          | There is              | There are           |
| 606         | 11          | look                  | looked              |
| 609         | 5           | CDD                   | CDC                 |
| 616         | 7           | time you think        | time do you think   |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: May 5, 2003

WITNESS: Marja-Liisa Hanninen

| Page | Line  | As Transcribed                           | Change To                                  |
|------|-------|--|--|
| 652  | 21-22 | the enrofloxacin                         | their infection                            |
| 663  | 4     | indicate                                 | indicated                                  |
| 666  | 1     | norfloxacin                              | norfloxacin                                |
| 666  | 2     | ciprofloxacin                            | ciprofloxacin                              |
| 666  | 5     | ciprofloxacin                            | ciprofloxacin                              |
| 670  | 1     | inhuman                                  | in human                                   |
| 670  | 16    | cerafloxacin                             | sarafloxacin                               |
| 672  | 9     | statement                                | statements                                 |
| 673  | 8     | flock                                    | flocks                                     |
| 673  | 14    | quite extensive                          | quite an extensive                         |
| 675  | 11    | so, if you think                         | so. I would think                          |
| 675  | 12    | those response.                          | dose/response.                             |
| 675  | 14    | those response.                          | dose/response.                             |
| 676  | 4     | there is difference                      | there is a difference                      |
| 676  | 13    | Your analysis                            | In your analysis                           |
| 676  | 18    | fluoroquinolone                          | fluoroquinolones                           |
| 677  | 18    | placed                                   | based                                      |
| 678  | 1     | end of '90s                              | end of the 90's                            |
| 686  | 13    | ciprofloxacin                            | ciprofloxacin                              |
| 691  | 20    | short on Sweden.                         | short follow-up on Sweden.                 |
| 694  | 8     | that                                     | then                                       |
| 699  | 1     | looking ahead                            | looking at that                            |
| 699  | 5     | seat                                     | stipulations                               |
| 700  | 12    | spacial                                  | spatial                                    |
| 700  | 13    | Han Deneeling                            | Han deNeeling                              |
| 700  | 21    | Diana                                    | Diane                                      |
| 703  | 2     | Not                                      | No   |
| 714  | 7     | acid in chemotherapeutic agents isolated | acid resistance in Campylobacters isolated |
| 718  | 13    | not same                                 | not the same                               |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: May 6, 2003

WITNESS: Mary Bartholomew

| Page | Line  | As Transcribed  | Change To   |
|------|-------|---|---|
| 730  | 7     | firm in Washington address  | firm's Washington address   |
| 730  | 13-14 | courts, Registry of Commonwealth.   | courts in the District of Columbia.   |
| 738  | 19    | stateholders  | stakeholders  |
| 739  | 12    | KPK   | CVM   |
| 740  | 3     | fluoroquinolone   | fluoroquinolone-resistant   |
| 740  | 9     | campylobacterial  | campylobacter   |
| 740  | 10    | eating chickens that were   | eating chickens, that were  |
| 740  | 11    | fluoroquinolone campylobacterial infection that   | fluoroquinolones, campylobacter infections that   |
| 740  | 13    | people who  | people, who   |
| 740  | 14    | provider and  | provider, and   |
| 741  | 21    | chicken that  | chicken, that   |
| 742  | 17    | discussed, were   | discussed, would  |
| 742  | 18    | in m questions  | in my questions   |
| 746  | 3     | attachment  | catchment   |
| 746  | 9     | when one wants to   | then one wants a  |
| 747  | 1     | welcomed  | welcome   |
| 747  | 6     | the ideal   | the "ideal  |
| 747  | 7     | incident  | incidence   |
| 747  | 8     | knowledge and   | knowledge of the  |
| 747  | 10    | diseases.   | disease."   |
| 747  | 15    | representatives   | representativeness  |
| 748  | 5     | detachment  | the catchment   |
| 751  | 15    | determinate   | determinant   |
| 753  | 7     | "multi - varied   | "multivariate   |
| 753  | 8-9   | population, attributable fractions, Campylobacteriosis case control study, 1998, 1999." | population attributable fractions, <i>Campylobacter</i> case control study, 1998-1999." |
| 753  | 10    | population, attributable  | population attributable   |
| 754  | 6     | population, attributable  | population attributable   |
| 754  | 9     | There's "A," undercooked or pink chicken.   | There's "Ate undercooked or pink chicken."  |
| 754  | 10    | "A" chicken prepared at home  | "Ate chicken prepared at home"  |
| 754  | 14    | "A," undercooked or pink  | "Ate undercooked or pink  |

|     |       |   |  |
|-----|-------|---|--|
|     |       | chicken,  | chicken",  |
| 754 | 22    | do with this  | do this  |
| 755 | 21    | FoodNet in  | FoodNet population in                                      |
| 756 | 12    | question  | questions  |
| 757 | 15    | rate  | rates  |
| 763 | 11-12 | on the evidence cause.                                | in evidence law.   |
| 763 | 18    | Registrar   | Register   |
| 763 | 21    | important considering                                 | important, considering                                     |
| 763 | 22    | outside home  | outside the home   |
| 764 | 2-3   | their dollars   | their food dollars   |
| 764 | 11    | rely.   | rely on.   |
| 768 | 16    | limitation is   | limitation of  |
| 768 | 17    | risks   | risk   |
| 768 | 18-19 | fraction."<br>Is it those cases that were             | fraction is that those cases that were                     |
| 768 | 20    | interest even   | interest, even   |
| 768 | 21    | been a cause of the disease,<br>could                 | been the cause of the disease,<br>would                    |
| 768 | 22    | risk thereby  | risk, thereby  |
| 769 | 1     | risk?   | risk".   |
| 769 | 22    | fraction but  | fraction, but  |
| 770 | 3     | ACRIORI   | <i>a priori</i>  |
| 772 | 16    | reduction   | fraction   |
| 774 | 4     | the "A" chicken prepared in                           | the "Ate chicken prepared at a                             |
| 774 | 5     | the restaurant has                                    | restaurant" has  |
| 774 | 6     | 44  | 24   |
| 774 | 9     | says, " 'A' chicken                                   | says, "Ate chicken   |
| 775 | 5     | respond, yes  | respond, "yes  |
| 775 | 6     | home would  | home "would  |
| 775 | 8     | said yes  | said "yes  |
| 775 | 9     | home than   | home" than   |
| 775 | 13    | cases for disease more<br>frequently from exposure to | cases get disease more frequently<br>from exposure than do |
| 776 | 7     | awfully   | awful  |
| 779 | 4     | attachment 29   | attachment 1   |
| 782 | 22    | Schmidt   | Schmid   |
| 783 | 3     | Schmidt, et al in                                     | Schmid, et al Study in                                     |
| 787 | 1     | ill less  | ill persons were less                                      |
| 787 | 7     | set of controls."                                     | set of controls. . . ."                                    |
| 787 | 10    | I said, more  | I said, ". . . more  |
| 787 | 11    | undercooked.  | undercooked."  |
| 788 | 18    | Schmitz study in Debuque                              | Schmid study in Dubuque                                    |
| 789 | 4     | Debuque   | Dubuque  |
| 790 | 10    | here. You're  | here. You  |
| 790 | 16    | as the question.                                      | ask the question.  |

|     |     |  |  |
|-----|-----|--|--|
| 790 | 19  | Rodriguez  | Rodrigues  |
| 791 | 5   | Rodriguez  | Rodrigues  |
| 791 | 17  | Rodriguez  | Rodrigues  |
| 791 | 20  | chicken," other than -- nor                          | chicken other than in restaurants nor                  |
| 791 | 21  | kitchen practices. We                                | kitchen hygiene practices." We                         |
| 792 | 18  | Schmitz  | Schmid   |
| 792 | 20  | Rodriguez  | Rodrigues  |
| 794 | 3   | epidemial  | endemic  |
| 794 | 22  | contamination  | contaminated   |
| 797 | 4   | CVC  | CDC  |
| 799 | 20  | separating out. This is                              | separating out --- this is                             |
| 800 | 8   | At if  | And if   |
| 802 | 8   | slip of  | flip of  |
| 802 | 18  | indication   | etiologic  |
| 803 | 9   | CVC  | CDC  |
| 803 | 21  | CVC  | CDC  |
| 804 | 13  | Floraquinolone                                       | fluoroquinolone  |
| 805 | 18  | Predence   | Friedman   |
| 805 | 19  | Predence   | Friedman   |
| 805 | 20  | CVC  | CDC  |
| 806 | 8-9 | Drank untreated water from a lake, river, or stream. | "Drank untreated water from a lake, river, or stream." |
| 806 | 19  | Floraquinolone                                       | fluoroquinolone  |
| 808 | 4   | solution   | sewage   |
| 809 | 11  | Norm's   | NARM's   |
| 810 | 14  | proposition trivial                                  | population attributable                                |
| 812 | 2   | know   | known  |
| 812 | 6   | resistant  | resistance   |
| 812 | 18  | talked maybe   | talked about how maybe                                 |
| 817 | 7   | come of  | come out of  |
| 819 | 19  | resistant of chicken                                 | resistant from chicken                                 |
| 821 | 13  | Ciprofloxacin  | ciprofloxacin  |
| 822 | 2   | it says number of                                    | it says "number of                                     |
| 822 | 3   | that indicated -- of                                 | with indicated pathogen" -- of                         |
| 822 | 4   | Ciprofloxacin -- 27; and it says                     | ciprofloxacin -- 37"; and it says                      |
| 822 | 9   | had -- one of the patients                           | had -- among patients                                  |
| 822 | 21  | "Of the  | "Among   |
| 822 | 22  | patients affected with campylobacter                 | patients who had only <i>campylobacter</i>             |
| 823 | 1   | isolate" --  | isolated..."   |
| 823 | 4   | Ciprofloxacin  | ciprofloxacin  |
| 824 | 7   | see. One of these patients, the                      | see. "One of these patients" ...the                    |
| 824 | 8   | -- for 7 days, having -- on                          | -- "for 7 days", having -- "on                         |
| 824 | 9   | resistant. The same isolate                          | resistant...." The "same isolate                       |

|     |    |   |  |
|-----|----|---|--|
| 824 | 10 | 2 days after Ciprofloxacin therapy was initiated. And | 10 days after ciprofloxacin therapy was initiated. A |
| 824 | 11 | Ciprofloxacin-susceptible species was isolated        | ciprofloxacin-susceptible...species was isolated     |
| 824 | 12 | at admission. That                                    | at admission; that                                   |
| 824 | 13 | four days.  | four days..."  |
| 825 | 10 | Aithromycin   | azithromycin   |
| 825 | 11 | Ciprofloxacin   | ciprofloxacin  |
| 825 | 20 | "Recovery   | "Recovered   |
| 826 | 1  | Azithromycin  | azithromycin   |
| 826 | 2  | Azithromycin  | azithromycin   |
| 826 | 3  | Ciprofloxacin   | ciprofloxacin  |
| 830 | 18 | Exhibit 9433.   | Exhibit G-953.                                       |
| 830 | 21 | Table 1.2?  | Table I.2?   |
| 831 | 4  | I think it's 1.2,                                     | I think it's I.2,                                    |
| 832 | 20 | MR. SPILLER:  | MR. NICHOLAS:  |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: May 6, 2003

WITNESS: Louis Cox, Jr.

| Page         | Line      | As Transcribed   | Change To   |
|--------------|-----------|--|---|
| 726          | 4         | Louie Cox, Jr.   | Louis Cox, Jr.  |
| 834          | 22        | Louie Anthony Cox, Jr.   | Louis Anthony Cox, Jr.  |
| 841          | 10        | her  | him   |
| 849          | 22        | checking consumption   | chicken consumption   |
| 850          | 14-15     | what are the causes of the associations.   | what are the causes of the associations?  |
| 853          | 10        | core six.  | course six.   |
| 854          | 9         | none exist.  | none exists.  |
| 856          | 18        | I rush to say  | I blush to say  |
| 866          | 3         | might tackle the approach  | might tackle the problem  |
| 867          | 9         | thought keys   | thought piece   |
| 869          | 3-5       | yet the probability that exactly one person will become ill may be less than the probably that two or more will become ill, right?   | "yet the probability that exactly one person will become ill may be less than the probably that two or more will become ill, right?"  |
| 869          | 14-15     | I did say this seems to me to be a very practical, sound approach. I have no remaining concern.  | I did say, "This seems to me to be a very practical, sound approach. I have no remaining concerns."   |
| 870          | 3-4       | They can be spacial clusters.  | There can be spacial clusters.  |
| 870          | 5         | Let me just say, not necessarily.  | Let me just say: not necessarily.   |
| 870 -<br>871 | 22 -<br>1 | if several people in the same family get sick, it's an outbreak.   | if several people in the same family get sick, is it an outbreak?   |
| 875 -<br>876 | 20 -<br>5 | It's the page on which the first complete sentence is, I mean -- like 10, it -- the study, the model -- it has to make a few baroque assumptions, K being the big one, to get across big data gaps, but it is very explicit about that. So all in all, I think that is a job well done. I want to invite you to critically examine | It's the page on which the first complete sentence is, I mean -- like 10, "It -- the study, the model -- it has to make a few baroque assumptions, K being the big one, to get across big data gaps, but it is very explicit about that. So all in all, I think that is a job well done. I want to invite you to critically |



|           |       |   |  |
|-----------|-------|---|--|
|           |       | a few assumptions if you share that conclusion.   | examine a few assumptions to see if you share that conclusion."  |
| 877       | 20-21 | the model says risk is equal to big K exposure  | the model says risk is equal to big K times exposure   |
| 878       | 18-19 | where you try to say is this model correct and useful.  | where you try to say, "Is this model correct and useful?"  |
| 878       | 20-21 | saying do its consequences follow from its premises,  | Saying, "Do its consequences follow from its premises?",   |
| 878       | 22    | empirically valid.  | empirically valid?   |
| 878 - 879 | 22-3  | So these comments are directed at a logical matter, if you would make the big K model work, a lot of little factors, that would be a terrific thing to do.  | So these comments are directed at a <i>logical</i> matter. If you could make the big K model work, a lot of little factors, that would be a terrific thing to do.  |
| 879       | 7     | On that, a somewhat imponderable question.  | Oh, that's a somewhat imponderable question.   |
| 880       | 19    | Virginia Misen  | Virginiamycin  |
| 883       | 20-21 | And that refers to the number of contracts.   | And that refers to a number of contracts.  |
| 888       | 9-12  | I've -- I don't know. It's not in deadline, I can tell you that. I don't think it was. And again, I tend to have some area of expertise. I think Bayer helped to -- Bayer, with some of the production costs. | I've -- I don't know. It's not, in my mind, I can tell you that. I don't think it was. And again, it's outside my area of expertise. I think Bayer helped out -- Bayer, with some of the production costs. |
| 890       | 14    | progression models  | regression models  |
| 892       | 1-3   | This is a reference for the rather-than-chicken assumption, per se, portion, not for the restaurant dining portion.   | This is a reference for the "rather-than-chicken consumption, per se" portion, not for the "restaurant dining" portion.  |
| 893       | 17    | And thirdly, the relation that you're referring to is   | And thirdly, if the relation that you're referring to is   |
| 894       | 10-12 | showing up as being significant -- don't be impressed by big odds ratio because of the logarithm scale that goes as low as zero but as high as 70.  | showing up as being significant. Don't be impressed by big odds ratio because of the logarithmic scale that goes as low as zero but as high as 70.   |
| 895       | 1     | I love that data step.  | I love that data set.  |
| 895       | 9     | Dr. Angelo's  | Dr. Angulo's   |
| 895       | 11    | Dr. Angelo's  | Dr. Angulo's   |
| 898       | 14-15 | This finding supports not the restaurant dining, but the not chicken per se point.  | This finding supports not the "restaurant dining", but the "not chicken per se" point.   |

|           |        |  |  |
|-----------|--------|--|--|
| 898       | 17-18  | My point is, why.  | My point is, Why?  |
| 899       | 13-14  | indicates that chicken at home -- I admit -- we haven't gotten down to business yet,   | indicates that chicken at home -- I admit, we haven't gotten down to business yet --   |
| 903       | 14-19  | The Eberhart-Phillips conclusion that you just mentioned uses common causes. Campylobacteriosis is a common disease with a number of common causes, the most important being, at least for campylobacteriosis in New Zealand, the most important being the consumption of undercooked chicken. | The Eberhart-Phillips conclusion that you just mentioned uses "common causes". "Campylobacteriosis is a common disease with a number of common causes, the most important being, [at least for campylobacteriosis in New Zealand], the most important being the consumption of undercooked chicken." |
| 903 - 904 | 22 - 1 | She is drawing a conclusion about causes.  | She is not drawing a conclusion about causes.  |
| 904       | 15-16  | I think there is probably a host of these interactions.  | I think there is probably a host-disease interaction.  |
| 905       | 7-10   | Let's see. There was no statistically significant risk associated with consumption of chicken other than in restaurants, nor with reported domestic kitchen hygiene factor.  | Let's see. "There was no statistically significant risk associated with consumption of chicken other than in restaurants, nor with reported domestic kitchen hygiene factor."  |
| 906       | 13     | logistic progression   | logistic regression  |
| 907       | 14-17  | Absolutely not. If you'll look at table 1 of Effler, you'll see on that on that page 3 of this exhibit you just handed me, from a restaurant there's an association in this model.   | Absolutely not. If you'll look at table 1 of Effler -- you'll see that on page 3 of this exhibit you just handed me -- from a restaurant there's an association in this model.   |
| 908       | 15     | math odds ratio  | matched odds ratio   |
| 910       | 11-14  | I state that he used a particular model conditional logistic progression without reporting the standard model diagnostics and tests that would roughly correspond to what I just said.   | I state that he used a particular model --conditional logistic regression -- without reporting the standard model diagnostics and tests that would roughly correspond to what I just said.   |
| 910       | 16     | how variable testing was done.   | how variable selection was done.   |
| 912       | 19     | No, it's seem to support.  | No, it's " <i>seem</i> to support".  |

ERRATA

In Re: ENROFLOXACIN FOR POULTRY: WITHDRAWAL OF APPROVAL OF BAYER CORPORATION'S NEW ANIMAL DRUG APPLICATION (NADA) 140-828 (BAYTRIL)

CASE NO.: 00N-1571

DATE TAKEN: May 7, 2003

WITNESS: Louis Cox, Jr.

| Page | Line  | As Transcribed  | Change To  |
|------|-------|---|--|
| 925  | 3     | Louie Cox, Jr.  | Louis Cox, Jr.   |
| 925  | 6     | LOUIE COX, JR.  | LOUIS COX, JR.   |
| 930  | 9     | Michael Bond  | Michael Vaughn   |
| 931  | 1     | Dr. DeGrowth.   | Dr. DeGroot.   |
| 931  | 19    | Dr. DeGrowth  | Dr. DeGroot  |
| 932  | 14    | Dr. DeGrowth  | Dr. DeGroot  |
| 937  | 5, 10 | Rodriguez   | Rodrigues  |
| 941  | 20    | Louie Cox, Jr.  | Louis Cox, Jr.   |
| 946  | 1     | reduction stage.  | production stage.  |
| 951  | 16    | Of course, minor effect demonstrates.   | Of course: "minor effect demonstrate(s)".  |
| 955  | 4     | I continued through, for example -- oh, here's where the log 10 comes in. For example, a reduction of three log 10 colony forming units per chicken.  | I continued through, "For example...". Oh, here's where the log 10 comes in: "For example, a reduction of three log 10 colony forming units per chicken..."  |
| 956  | 11    | What I show is not a quote but which is pertinent and reflects the point there is that the effect of such a decrease in the number -- it's a pretty large decrease in the number of campylobacter would not have been detected by the -- what he refers to as "qualitative methods," meaning the prevalence metric. | What I show is not a quote, but -- which is pertinent and reflects the point there -- is that the effect of such a decrease in the number (it's a pretty large decrease in the number of campylobacters) would not have been detected by the -- what he refers to as "qualitative methods," meaning the prevalence metric. |
| 962  | 4     | represents using  | represents, using  |
| 966  | 11    | several things on here  | several things going on here   |
| 967  | 6     | In all of the cases, if I'm not referring to figures, specialized to the context such as 7(a) and 7(b) and something that I pull out, or if a reference, for example, a number is given, reference 17, that's not pertinent to the content, I would not feel obliged to repeat those                                | In all of the cases, if I'm not referring to figures (specialized to the context, such as 7(a) and 7(b), and something that I pull out); or if a reference -- for example, a number is given, reference 17, that's not pertinent to the content -<br>- I would not feel obliged to   |

|     |    |   |   |
|-----|----|---|---|
|     |    | typographical marks in the quoted section -- for example, in a journal article.   | repeat those typographical marks in the quoted section, for example, in a journal article.  |
| 968 | 8  | I think that correcting the punctuation and putting in the S -- I think that's fair. The how to deal with the sentence break around the deleted figure reference, in light of our long discussion, I question in my own mind whether it would have been useful to have quoted the entire thing either though that would be duplicating material already in there. | I think that correcting the punctuation and putting in the S, I think that's fair. The how to deal with the sentence break around the deleted figure reference... In light of our long discussion, I question in my own mind whether it would have been useful to have quoted the entire thing, either, though that would be duplicating material already in there. |
| 969 | 11 | looks to me that this   | looks to me like this   |
| 970 | 11 | as a form for   | as a farm-to-fork   |
| 971 | 1  | and that Rosenquist demonstrates is not linear is   | and that Rosenquist demonstrates is not linear -- is  |
| 971 | 4  | microbial lode  | microbial load  |
| 971 | 10 | Prevalence says not how many microbes is this chicken carrying; prevalence says what fraction of flocks in this case have at least some campylobacter present.  | Prevalence says not, "How many microbes is this chicken carrying?" Prevalence says, "What fraction of flocks in this case have at least some campylobacter present?"  |
| 972 | 16 | microbial load has held constant  | microbial load is held constant   |
| 972 | 18 | microbial load, such as all the situations I'm looking at where Enrofloxacin use is contemplated.   | microbial load... such as all the situations I'm looking at, where Enrofloxacin use is contemplated.  |
| 973 | 21 | So for you to say that CVM incorporates an important component is to leave out everything important which is in simulation runs where microbial load doesn't change, for example, because there's no manipulation of Enrofloxacin use.  | So for you to say that "CVM incorporates an important component" is to leave out everything important which is in simulation runs where microbial load doesn't change -- for example, because there's no manipulation of Enrofloxacin use.  |
| 975 | 21 | A An approximately linear relationship for these simulations. The reason I'm saying that is it's not a general relationship. It's a relationship conditioned on what we just talked about, which is holding microbial load constant.  | A An approximately linear relationship for <i>these</i> simulations. The reason I'm saying that is, it's not a <i>general</i> relationship. It's a relationship conditioned on what we just talked about -- which is holding microbial load constant.   |
| 976 | 8  | Actually, not necessarily, but  | Actually, not necessarily. But  |

|     |            |  |   |
|-----|------------|--|---|
|     |            | <p>you're falling into I think just the perhaps confusion that I was trying to clarify which is these are not general relationships. These are plots of perhaps 8 different simulation run outputs.</p> <p>To that, you're trying to attach a general rule which is that human illness is proportional to flock prevalence. I'm telling you that general rule is an incorrect generalization because in general, microbial loads are not held constant as they are in these simulations.</p> | <p>you're falling into I think just the, perhaps, confusion that I was trying to clarify, which is: these are <i>not</i> general relationships. These are plots of perhaps 8 different simulation run outputs.</p> <p>To that, you're trying to attach a general rule, which is that human illness is proportional to flock prevalence. I'm telling you: that general rule is an incorrect generalization because, in general, microbial loads are <i>not</i> held constant as they are in these simulations.</p> |
| 980 | 1          | I was hung up on which of the many assumptions, some explicit, some subsequently described, by CVM as being implicit but not explicitly stated you were thinking of.   | I was hung up on which of the many assumptions -- some explicit, some subsequently described, by CVM, as being implicit but not explicitly stated -- you were thinking of.  |
| 981 | 2          | Rodriguez  | Rodrigues   |
| 982 | 16, 16, 21 | Rodriguez  | Rodrigues   |
| 982 | 20         | Almost. The demonstrably is only partially covered. I'd say for Rodriguez it's suggested.  | Almost. The "demonstrably" is only partly covered. I'd say for Rodrigues, it's suggested.   |
| 983 | 3, 4, 19   | Rodriguez  | Rodrigues   |
| 984 | 13, 14, 20 | Rodriguez  | Rodrigues   |
| 984 | 14         | I cite Rodriguez to support the idea travel abroad and consumption of chicken in a restaurant are associated with being a cause,   | I cite Rodriguez to support the idea that travel abroad and consumption of chicken in a restaurant are associated with being a case,  |
| 985 | 1          | Well, again, what Rodriguez says, being careful to exactly quote his words, in the abstract on page 1, fourth line, sentence starting at the end of that line, where travel, he says two things -- two main things. Travel abroad and consumption of   | Well, again, what Rodriguez says (being careful to exactly quote his words), in the abstract on page 1, fourth line, sentence starting at the end of that line, where travel - - he says two things -- two main things: Travel abroad, and  |

|      |             |  |   |
|------|-------------|--|---|
|      |             | chicken in a restaurant were statistically associated with being a cause -- so yes, he talks about chicken in a restaurant.  | consumption of chicken in a restaurant, were statistically associated with being a cause. So yes, he talks about chicken in a restaurant.   |
| 985  | 1           | Rodriguez  | Rodrigues   |
| 986  | 1           | And as I said, I cited myself and my own causal analysis for the demonstrably part   | And as I said, I cited myself and my own causal analysis for the "demonstrably" part  |
| 986  | 6, 7, 8, 17 | Rodriguez  | Rodrigues   |
| 987  | 18          | Rodriguez  | Rodrigues   |
| 992  | 6           | This article doesn't discuss or this abstract doesn't discuss whether the design is prospective, saying if you have poor kitchen hygiene are you more likely to get campylobacteriosis or whether it's retrospective, meaning if you got campylobacteriosis, it's more likely that you had poor kitchen hygiene. | This article doesn't discuss (or this abstract doesn't discuss) whether the design is <i>prospective</i> -- saying if you have poor kitchen hygiene, are you more likely to get campylobacteriosis? -- or whether it's <i>retrospective</i> , meaning: if you got campylobacteriosis, it's more likely that you had poor kitchen hygiene. |
| 992  | 15          | This may be showing if you ask people who are sick, hey, did you wash your hands, more of them will say no, which is the point -- the distinction I was aiming at before.  | This may be showing, if you ask people who are sick, "Hey, did you wash your hands?", more of them will say no -- which is the point, the distinction, I was aiming at before.  |
| 993  | 10          | What it could be showing is that people who are asked, after they become cases, did you wash your cutting board, are more likely to respond no.  | What it could be showing is that people who are asked, after they become cases, "Did you wash your cutting board?" are more likely to respond "No".   |
| 994  | 15          | I don't think that's correct, but -- and the reason is what exactly does "unattributed" mean here. you know, is it unattributed because there was no evidence that this was the source?  | I don't think that's correct. But -- and the reason is, what exactly does "unattributed" mean here? You know, is it "unattributed" because there was no evidence that this was the source?  |
| 999  | 4           | I didn't say which I interpreted. Which I know, as I sit here, interpret as an average, yes, per capita.   | I didn't say "which I interpreted". Which I now, as I sit here, interpret as an average -- yes, per capita.   |
| 999  | 17          | NOO page.  | NOOH.   |
| 1000 | 1           | You mean the risk assessment   | You mean the risk assessment  |

|      |    |  |  |
|------|----|--|--|
|      |    | itself or the CVM assessment?  | itself or what CVM said about its risk assessment?   |
| 1000 | 6  | represents their use of what they meant about it.  | represents their use, i.e., what they meant about it.  |
| 1001 | 13 | No. I'm not looking for those words. I am looking for these words: human health impact, lamda, is equal to some constant, k-res, times the pounds of chicken consumed with Fluoroquinolone-resistant campylobacter. And my point is that this is describing risks to a typical on average a representative consumer. | No. I'm not looking for those words. I am looking for these words: human health impact, lambda, is equal to some constant, k-res, times the pounds of chicken consumed with Fluoroquinolone-resistant campylobacter. And my point is that this is describing risks to a typical or average or representative consumer. |
| 1001 | 20 | I know that's been stated and, you know, what's not here is what is the distribution of exposures for different people.  | I know that's been stated. And, you know, what's <i>not</i> here is: What is the distribution of exposures for different people?   |
| 1003 | 13 | Yes. For example, you could say this is a, quote, hypothetical. It wouldn't have to be that somebody actually said that --   | Yes. For example, you could say this is a, quote, "hypothetical". It wouldn't have to be that somebody actually said that --   |
| 1006 | 11 | And that does not establish a relation between them, again, quoting from all the written discussion on this, in any meaningful or useful sense.  | And that does not "establish" a "relation" between them, again quoting from all the written discussion on this, in any meaningful or useful sense.   |
| 1006 | 21 | I believe that the examples are -- I attempt to suggest that the aggregate -- I'm sorry -- the ratio of aggregate level of campylobacteriosis cases to the aggregate level of chicken consumption has not been shown to have any stronger causal connection than other ratios, including manifestly ridiculous ones. | I believe that the examples are. I attempt to suggest that the aggregate...I'm sorry. The ratio of aggregate level of campylobacteriosis cases to the aggregate level of chicken consumption has not been shown to have any stronger <i>causal</i> connection than other ratios, including manifestly ridiculous ones. |
| 1008 | 4  | A When I reviewed this model in 1999, was I not -- when I reviewed the risk assessment I certainly read what was written about the design.   | A When I reviewed this model in 1999, was I not? When I reviewed the risk assessment I certainly read what was written about the design.   |
| 1010 | 10 | As you will -- I'm sorry -- and you will notice that the big assumption is that the incidence of bad   | "As you will" -- I'm sorry. "And you will notice that the big assumption is that the incidence   |

|      |           |   |   |
|------|-----------|---|---|
|      |           | outcomes more formally in response that we don't want is proportional to the volume of outgoing chicken informally the exposure, or something proportional to exposure.   | of bad outcomes [more formally, of <i>response</i> ] that we don't want is proportional to the volume of outgoing chicken [informally the <i>exposure</i> , or something proportional to exposure].   |
|      |           | Right. It's exposure and undesirable or bad effect, not dose response.  | Right. It's "exposure" and "undesirable (or bad) effect", not "dose" and "response".  |
| 1014 | 14        | I spoke informally of munging together different parameters, said this was something that needed to be checked out.   | I spoke informally of "munging together different parameters" and said this was something that needed to be checked out.  |
| 1015 | 3         | First thing is to be correct.   | The first thing is to be correct.   |
| 1015 | 10        | making it open and inspectable and documenting the assumptions is all good things.  | making it open and inspectable and documenting the assumptions are all good things.   |
| 1024 | 3         | When you say your model, this is an early version.  | When you say "your model", this is an early version.  |
| 1024 | 13        | It depends if you're referring to Cox 2002, then it was the 2002 model.   | It depends. If you're referring to Cox 2002, then it was the 2002 model.  |
| 1028 | 11        | my statement that sensitivity analysis provides partial solution to the problem of unknown variable dose response relations.  | my statement that "Sensitivity analysis provides a partial solution to the problem of unknown and variable dose response relations."  |
| 1031 | 1         | What I was not relying on as I have clearly written is any assumption that there can't be any risk below 500 CFUs. And as I've written in Exhibit B-1629 on page 36, any dose response relation with these qualitative features that are discussed tends to produce similar expected number of CB cases from given population frequency distribution microbial loads. | What I was <i>not</i> relying on, as I have clearly written, is any assumption that there can't be any risk below 500 CFUs. And, as I've written in Exhibit B-1629 on page 36, <i>any</i> dose response relation with these qualitative features (that are discussed) tends to produce similar expected number of CP cases from a given population frequency distribution of microbial loads. |
| 1034 | 3, 15, 22 | Tunis   | Teunis  |
| 1035 | 14, 22    | Tunis   | Teunis  |
| 1037 | 1         | Tunis   | Teunis  |
| 1039 | 11,       | Tunis   | Teunis  |



|      |           |  |   |
|------|-----------|--|---|
|      | 14        |  |   |
| 1040 | 17        | Tunis  | Teunis  |
| 1042 | 13,<br>16 | Tunis  | Teunis  |
| 1042 | 18        | You know, I could find myself with a range of data.  | You know, I confined myself to the range of the data.   |
| 1043 | 14,<br>18 | Tunis  | Teunis  |
| 1044 | 7         | Tunis  | Teunis  |
| 1044 | 12        | <p>My model states -- or my description and discussion of exactly this issue in my model states that risks are low or zero. They don't have to be zero, they can be low for sufficiently small doses, e.g., less than 500 CFUs, doesn't have to be 500 CFUs, and illness probability increases rapidly as a function of dose reaching an approximate plateau -- this is now describing why I deal with this model in my model -- it reaches an approximate plateau of about .2 for CFU levels of about a thousand to 10,000 CFUs.</p> <p>What I've said is by doing sensitivity analyses, I've found that any dose response model that captures the rough qualitative features of the data will suffice.</p> | <p>Well, no. My model states (or my description and discussion of exactly this issue in my model states) that risks are low or zero. They don't have to be zero. They can be low for sufficiently small doses, e.g., less than 500 CFUs -- it doesn't have to be 500 CFUs. And illness probability increases rapidly as a function of dose, reaching an approximate plateau. This is now describing how I deal with this model in my model -- it reaches an approximate plateau of about .2 for CFU levels of about a thousand to 10,000 CFUs.</p> <p>What I've said is: by doing sensitivity analyses, I've found that <i>any</i> dose response model that captures the rough qualitative features of the data will suffice.</p> |
| 1045 | 13        | Popkin   | Popken  |
| 1046 | 1         | Tunis  | Teunis  |
| 1047 | 11        | <p>If you look at those data, you'll see that assuming that there's zero response to zero dose, the pattern as far as we know is that not much happens and I don't believe that there are data for humans below about 500 CFUs. Well, not in this experiment.</p> <p>Basically, not much happens until you get up to a few hundred CFUs, then about 20 percent of people get sick. So I think that these data from one</p>   | <p>If you look at those data, you'll see that, assuming that there's zero response to zero dose, the pattern as far as we know is that not much happens (and I don't believe that there are data for humans below about 500 CFUs -- well, not in this experiment) -- basically, not much happens until you get up to a few hundred CFUs. Then about 20 percent of people get sick. So, I think that these data from one feeding study</p>   |

|      |    |  |  |
|------|----|--|--|
|      |    | feeding study -- it's hard to know what to make of them but they're consistent with the idea that there's a higher response probability when you have several hundred, several thousand CFUs. And we don't really know what happens in the low dose range.                         | -- it's hard to know what to make of them, but they're consistent with the idea that there's a higher response probability when you have several hundred, several thousand CFUs. And we don't really know what happens in the low-dose range.  |
| 1048 | 12 | Tunis  | Teunis   |
| 1051 | 4  | and there has subsequently been peer review to published.  | and that has subsequently been peer reviewed and published.  |
| 1052 | 5  | are extremely robust, the assumptions.   | are extremely robust to the assumptions.   |
| 1053 | 21 | a bilinear probability   | a binomial probability   |
| 1054 | 2  | For the next one down, another bilinear distribution,  | For the next one down, another binomial distribution,  |
| 1054 | 4  | For the surface microbial load which starts to get exciting from a cause and effect point of view, as specified, a triangular distribution for the lot of 10 of the values.  | For the surface microbial load (which starts to get exciting from a cause-and-effect point of view), as specified, a triangular distribution for the log of 10 of the values.  |
| 1055 | 11 | And there's a substantial framework that these piece by piece steps get into to justify that dual role and that is the framework outlined in the exhibit that I just referred to, the B-1020 -- in my book.  | And there's a substantial framework that these piece-by-piece steps fit into to justify that dual role. And that is the framework outlined in the exhibit that I just referred to, the B-1020 - - in my book.  |
| 1056 | 22 | In this role of the table, yes.  | In this row of the table, yes.   |
| 1060 | 4  | This is a matter of what the operational definition of the numbers mean. My operational, I mean what measurement procedures are we using.  | This is a matter of the <i>operational definition</i> of what the numbers mean. By "operational" I mean, what measurement procedures are we using?   |
| 1063 | 10 | The point there is that mean variance for each step in a process where a number of factors are being multiplied is sufficient when there are a large number of steps, as there are here, fully characterize the distribution, the meaning of the variance for the overall process. | The point there is that the mean and variance for each step in a process where a number of factors are being multiplied is sufficient (when there are a large number of steps, as there are here) to fully characterize the distribution, the mean and variance for the overall process. |
| 1063 | 22 | I believe that reads like a geometric medium   | I believe that reads like a geometric median   |

|      |    |  |  |
|------|----|--|--|
| 1066 | 10 | For example, this would be incorrect if the population had a certain distribution,   | For example, this would be incorrect if the population had a Cauchy distribution,  |
| 1068 | 4  | The sample limit theorem that I referred to deals with the composition of multiple multiplicative steps.   | The specific central limit theorem that I referred to deals with the composition of multiple multiplicative steps.   |
| 1069 | 3  | It's only partially derived but there's a much simpler argument to getting there that's much more data driven.   | It's only partially derived. But there's a much simpler argument for getting there that's much more data driven.   |
| 1070 | 21 | No, I didn't rely on it because you might be able to remove one or two points and change the answer in something that only has 7 data points. What I relied on was the underlying data, which is a lot richer but this is the simplest way of showing the results.   | No, I didn't rely on it, because you might be able to remove one or two points and change the answer, in something that only has 7 data points. What I relied on was the underlying data, which is a lot richer. But this is the simplest way of showing the results.  |
| 1071 | 5  | You picked the regression equation for this?   | Who picked the regression equation for this?   |
| 1071 | 6  | The statistics package that I was using in the upper not clearly legible margin of the picture.  | The statistics package that I was using (in the upper, not clearly legible, margin of the picture.)  |
| 1072 | 7  | What I'm saying is if you take the simplest possible look at the data, you'll see it doesn't look anything like straight line sloping upward to the right  | What I'm saying is: If you take the simplest possible look at the data, you'll see it doesn't look anything like a straight line sloping upward to the right.  |
| 1073 | 10 | I don't think I used the jargon exploratory data analysis. I think I have indicated in multiple places that the simplest way of looking at the data that the hypothesis, that it's a cluster around a straight line leaning from the lower left corner upwards has no relation to the real data even when you look at it in the simplest possible way. | I don't think I used the jargon "exploratory data analysis". I think I have indicated in multiple places that with the simplest way of looking at the data, that the hypothesis (that it's a cluster around a straight line leaning from the lower left corner upwards) has no relation to the real data, even when you look at it in the simplest possible way. |
| 1074 | 11 | Well, this testimony was written with hyperlink in it and they were very close based on hyperlink but I'm not sure how close they are in terms of pages.   | Well, this testimony was written with hyperlinks in it, and they were very close based on hyperlinks. But I'm not sure how close they are in terms of pages.   |
| 1076 | 11 | aggression   | regression   |

|      |       |                                      |  |
|------|-------|--------------------------------------|--|
| 1079 | 6     | little slow to go along with either. | little loathe to go along with "either". |
| 1079 | 14    | one forces -- use                    | one forces it -- use                     |
| 1080 | 6     | is you should                        | is, you should                           |
| 1082 | 14-15 | mark for exhibit                     | mark for an exhibit                      |
| 1085 | 11    | FDA.                                 | USDA.                                    |
| 1089 | 3     | the human health risk, is            | that human health risk is                |
| 1090 | 10    | it in a                              | it as a                                  |
| 1092 | 15    | predictable                          | predicting                               |
| 1093 | 11    | totally private?                     | totally in private?                      |
| 1093 | 13    | about we should                      | about how we should                      |
| 1095 | 12    | Rodriguez                            | Rodrigues                                |
| 1095 | 15    | raw data and                         | raw data, and                            |
| 1095 | 16    | that data as                         | that data, as                            |
| 1098 | 2     | being not clear.                     | not being clear.                         |
| 1098 | 14    | Rodriguez                            | Rodrigues                                |
| 1103 | 10    | controlled                           | control                                  |
| 1105 | 12    | Erisycolitis                         | air sacculitis                           |
| 1105 | 12    | Erisycolitis                         | air sacculitis                           |
| 1106 | 4     | Erisycolitis                         | air sacculitis                           |
| 1108 | 3, 21 | Rodriguez                            | Rodrigues                                |
| 1108 | 5     | are saying it doesn't                | are saying: "it doesn't                  |
| 1108 | 6     | it be, why didn't things             | it be? Why didn't things                 |
| 1108 | 7     | drug.                                | drug?"                                   |
| 1113 | 2     | your                                 | you're                                   |
| 1114 | 20    | called eight chick.                  | called "ate" chick.                      |
| 1114 | 21    | Eight chick,                         | "Ate chick",                             |
| 1116 | 17    | classification, vis farm, you got    | classification "vis farm", you got       |

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

In the Matter of:

**Enrofloxacin for Poultry:  
Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828**

**FDA DOCKET: 00N-1571**

**Date: June 6, 2003**

**ORDER**

On June 6, 2003, Respondent Bayer Corporation submitted proposed corrections in the transcript of oral testimony in this matter. The proposed corrections were limited to correcting transcription errors. It appearing that each of the proposed corrections is justified, it is ORDERED that corrections be made to the official transcript of oral testimony as follows:

**WITNESS: Linda Tollefson**

**DATE TAKEN: April 28, 2003**

| Page | Line | As Transcribed    | Change To          |
|------|------|-------------------|--------------------|
| 27   | 19   | Cerofloxacin      | Sarafloxacin       |
| 28   | 15   | fluoroquinolones; | fluoroquinolones”; |
| 36   | 7    | Greg,             | Gregg,             |
| 52   | 10   | TOPES             | Tauxe’s            |
| 55   | 4    | of ruse           | for use            |
| 55   | 6    | Freedman          | Friedman           |
| 56   | 19   | CVM BOSE          | CVM/Vose           |
| 57   | 1    | CVM BOSE          | CVM/Vose           |
| 61   | 2    | Dr. Freedman      | Dr. Friedman       |
| 61   | 22   | this come         | this comes         |
| 62   | 5    | “8 Chicken        | . Ate chicken      |
| 63   | 6    | Freedman          | Friedman           |
| 64   | 14   | Freedman          | Friedman           |
| 66   | 22   | Freedman          | Friedman           |

06:07:03 JUN -6 PM '03

|     |    |                |                 |
|-----|----|----------------|-----------------|
| 67  | 17 | Freedman's     | Friedman's      |
| 70  | 13 | Homberg        | Holmberg        |
| 70  | 14 | Taket          | Tacket          |
| 70  | 14 | Conan Talkes   | Cohen and Tauxe |
| 70  | 14 | Bivey          | Bibi            |
| 71  | 1  | Homberg        | Holmberg        |
| 71  | 10 | Taket          | Tacket          |
| 71  | 20 | Conan Talkes   | Cohen and Tauxe |
| 72  | 2  | Bivey          | Bibi            |
| 75  | 11 | bed            | be              |
| 82  | 4  | lori           | lari            |
| 94  | 13 | Minnick's      | Minnich's       |
| 97  | 3  | D-             | B-              |
| 100 | 1  | understanding  | understand      |
| 107 | 9  | from2000       | from 2000       |
| 108 | 8  | laundry        | monitoring      |
| 120 | 5  | non-typoid     | non-typhoid     |
| 120 | 8  | typing         | typhi           |
| 120 | 9  | non-typing     | non-typhi       |
| 120 | 13 | non-typing     | non-typhi       |
| 121 | 8  | One week       | One per week    |
| 134 | 12 | Which          | Would           |
| 137 | 9  | thank          | to              |
| 137 | 22 | the            | that            |
| 140 | 18 | founded        | rounded         |
| 153 | 13 | no             | not             |
| 154 | 8  | Glysson        | Glisson         |
| 154 | 19 | Glysson's      | Glisson's       |
| 154 | 21 | Glysson's      | Glisson's       |
| 155 | 8  | Glysson's      | Glisson's       |
| 155 | 12 | Glysson's      | Glisson's       |
| 157 | 4  | Glysson        | Glisson         |
| 157 | 12 | ADUCA          | AMDUCA          |
| 159 | 9  | ADUCA          | AMDUCA          |
| 162 | 21 | ops            | authors         |
| 165 | 15 | Dr. Freedman   | Dr. Friedman    |
| 166 | 14 | Dr. Freedman   | Dr. Friedman    |
| 168 | 1  | Freedman       | Friedman        |
| 170 | 22 | Guilliam-Barre | Guillain-Barre  |
| 171 | 2  | lead           | Mead            |
| 171 | 11 | lead           | Mead            |
| 182 | 1  | Guilliam-Barre | Guillain-Barre  |
| 182 | 4  | Guilliam-Barre | Guillain-Barre  |

**WITNESS:** Robert Walker

**DATE TAKEN:** April 29, 2003

| <b>Page</b> | <b>Line</b> | <b>As Transcribed</b>         | <b>Change To</b>                 |
|-------------|-------------|-------------------------------|----------------------------------|
| 188         | 12          | CVC                           | CDC                              |
| 188         | 14          | turnover                      | Tenover                          |
| 189         | 4           | proto-formula,                | protocol                         |
| 189         | 11          | CVC                           | CDC                              |
| 203         | 1           | free agents                   | reagents                         |
| 204         | 1           | micro-organisms               | microorganisms                   |
| 204         | 12          | micro-organisms               | microorganisms                   |
| 205         | 14          | micro-organism                | microorganism                    |
| 207         | 15          | Amacrolyte                    | macrolide                        |
| 210         | 19          | gastral enteritis             | gastroenteritis                  |
| 210         | 19          | and                           | an                               |
| 210         | 22          | And is what's                 | And it is what's                 |
| 217         | 9           | am I offered it?              | am I off of it?                  |
| 217         | 12          | Am I offered it?              | Am I off of it?                  |
| 222         | 9           | CVC                           | CDC                              |
| 222         | 10          | CVC                           | CDC                              |
| 236         | 5           | enterobacteriosis,            | Enterobacteriaceae               |
| 238         | 13          | gastro-enteritis              | gastroenteritis                  |
| 238         | 18          | pharmaco-kinetic              | pharmaco-kinetics                |
| 243         | 20          | whether that antimicrobial is | whether that an antimicrobial is |

**WITNESS:** Frederick Angulo

**DATE TAKEN:** April 30, 2003

| <b>Page</b> | <b>Line</b> | <b>As Transcribed</b>         | <b>Change To</b>                           |
|-------------|-------------|-------------------------------|--|
| 267         | 10          | attachment.                   | attachments.                               |
| 268         | 16          | jejune                        | jejuni                                     |
| 269         | 22          | offer                         | author                                     |
| 271         | 22          | till                          | until                                      |
| 272         | 2           | till                          | until                                      |
| 279         | 11          | date versus                   | data versus                                |
| 279         | 11          | date which                    | data which                                 |
| 285         | 1           | apriority                     | a priori                                   |
| 289         | 15          | fluoroquinolone Campylobacter | fluoroquinolone resistant<br>Campylobacter |
| 293         | 16          | grahms                        | gram                                       |
| 294         | 2           | Chicatoxin                    | shiga toxin                                |
| 294         | 5           | Chagilla                      | Shigella                                   |
| 294         | 17          | Chagilla                      | Shigella                                   |
| 296         | 16          | Campyl                        | Campylobacter                              |
| 306         | 4           | Hard Net                      | Hardnett                                   |
| 306         | 16          | site                          | cite                                       |

|     |    |  |                     |
|-----|----|--|---------------------|
| 309 | 1  | HardNet                                    | Hardnett            |
| 310 | 3  | Hard Net                                   | Hardnett            |
| 322 | 7  | call                                       | all                 |
| 322 | 8  | venting                                    | vetting             |
| 338 | 1  | or E. coli                                 | or coli             |
| 344 | 19 | grahms                                     | grams               |
| 345 | 12 | juni                                       | jejuni              |
| 345 | 17 | to juni                                    | jejuni              |
| 345 | 18 | coli so we                                 | coli we             |
| 346 | 4  | isolate                                    | isolates            |
| 348 | 16 | milligrams                                 | micrograms          |
| 349 | 1  | resistant                                  | resistance          |
| 351 | 21 | or   | for                 |
| 353 | 11 | had an effective                           | had ineffective     |
| 360 | 3  | aggression                                 | regression          |
| 362 | 12 | is approximation                           | is an approximation |
| 374 | 22 | juni                                       | jejuni              |
| 395 | 13 | 1, 028                                     | 1,028               |
| 395 | 15 | was89                                      | was 89              |
| 399 | 9  | as   | is                  |
| 404 | 10 | controlled                                 | control             |
| 414 | 20 | Alteri                                     | poultry             |
| 431 | 20 | MR. NICHOLAS                               | MR. SPILLER         |
| 433 | 1  | 899  | A-99                |
| 448 | 17 | medium                                     | median              |
| 449 | 22 | resistance                                 | resistant           |
| 450 | 15 | -- whether you know whether you controlled | -- Smith controlled |
| 461 | 2  | apriority                                  | a priori            |
| 462 | 10 | apriority                                  | a priori            |
| 462 | 12 | apriority                                  | a priori            |
| 463 | 5  | apriority                                  | a priori            |

**WITNESS:** Kirk Smith

**DATE TAKEN:** May 1, 2003

| Page | Line | As Transcribed                | Change To                         |
|------|------|-------------------------------|-----------------------------------|
| 483  | 7    | of the corporation.           | of the Bayer Corporation.         |
| 484  | 3    | norms                         | NARMS                             |
| 484  | 7    | scan.                         | scheme.                           |
| 488  | 19   | conducting cross examination. | conducting the cross-examination. |
| 491  | 21   | jurist?                       | reviewer?                         |
| 492  | 12   | review                        | reviewer                          |
| 494  | 6    | former                        | formal                            |
| 494  | 18   | methods analytical            | methods and analytical            |



|     |       |                           |                                  |
|-----|-------|---------------------------|----------------------------------|
| 494 | 20    | that was you              | that you                         |
| 494 | 21    | all of those defined      | all of those been defined        |
| 497 | 4     | Embry,                    | Emery,                           |
| 498 | 5-6   | what information he got   | what information the witness got |
| 498 | 6     | he                        | they                             |
| 503 | 2     | Pyddic, Gunn,             | Piddock, Gaunt,                  |
| 503 | 3     | Thruolphal,               | Threlfall,                       |
| 503 | 4     | Thruolphal                | Threlfall                        |
| 504 | 5     | Pro crit                  | purpose                          |
| 505 | 11    | there prospective as      | this prospective, as             |
| 505 | 12    | got control               | got a control                    |
| 505 | 16    | there                     | it                               |
| 507 | 11    | using nalidixic           | using a nalidixic                |
| 508 | 1     | genes.                    | genus.                           |
| 508 | 2     | genes?                    | genus?                           |
| 513 | 8     | with                      | were                             |
| 516 | 19    | TCR                       | PCR                              |
| 521 | 5     | flore-typing              | fla typing                       |
| 521 | 14    | great.                    | correct.                         |
| 523 | 11    | to                        | as                               |
| 524 | 14-15 | sources in poultry        | sources in particular poultry    |
| 530 | 19    | forms                     | subtypes                         |
| 536 | 2     | flaw                      | fla                              |
| 536 | 5     | flaw-typing               | fla typing                       |
| 536 | 8     | Nachompkin                | Nachamkin                        |
| 536 | 10    | following in the          | following the                    |
| 536 | 11    | Nachompkin                | Nachamkin                        |
| 536 | 15    | flaw                      | fla                              |
| 536 | 20    | Flaw                      | Fla                              |
| 536 | 20    | F-L-A-W.                  | F-L-A.                           |
| 536 | 21    | Flaw                      | Fla                              |
| 538 | 7     | But wouldn't you consider | But you wouldn't consider        |
| 538 | 20    | detection                 | detected                         |
| 547 | 7     | we can die of variables   | we can divide variables          |
| 547 | 9     | flawed                    | fla                              |
| 556 | 6     | FLAG                      | FLA                              |

**WITNESS:** Heidi Kassenborg

**DATE TAKEN:** May 2, 2003

| <b>Page</b> | <b>Line</b> | <b>As Transcribed</b> | <b>Change To</b>    |
|-------------|-------------|-----------------------|---------------------|
| 567         | 17          | packaging             | pathogens           |
| 572         | 2           | CBM's                 | CVM's               |
| 573         | 5           | draft                 | direct              |
| 578         | 13          | infectious diseases   | Infectious Diseases |

WITNESS: Mary Bartholomew

DATE TAKEN: May 6, 2003

| Page | Line  | As Transcribed  | Change To   |
|------|-------|---|---|
| 730  | 7     | firm in Washington address  | firm's Washington address   |
| 730  | 13-14 | courts, Registry of Commonwealth.   | courts in the District of Columbia.   |
| 738  | 19    | stateholders  | stakeholders  |
| 739  | 12    | KPK   | CVM   |
| 740  | 3     | fluoroquinolone   | fluoroquinolone-resistant   |
| 740  | 9     | campylobacterial  | campylobacter   |
| 740  | 10    | eating chickens that were   | eating chickens, that were  |
| 740  | 11    | fluoroquinolone campylobacterial infection that   | fluoroquinolones, campylobacter infections that   |
| 740  | 13    | people who  | people, who   |
| 740  | 14    | provider and  | provider, and   |
| 741  | 21    | chicken that  | chicken, that   |
| 742  | 17    | discussed, were   | discussed, would  |
| 742  | 18    | in m questions  | in my questions   |
| 746  | 3     | attachment  | catchment   |
| 746  | 9     | when one wants to   | then one wants a  |
| 747  | 1     | welcomed  | welcome   |
| 747  | 6     | the ideal   | the "ideal  |
| 747  | 7     | incident  | incidence   |
| 747  | 8     | knowledge and   | knowledge of the  |
| 747  | 10    | diseases.   | disease."   |
| 747  | 15    | representatives   | representativeness  |
| 748  | 5     | detachment  | the catchment   |
| 751  | 15    | determinate   | determinant   |
| 753  | 7     | "multi - varied   | "multivariate   |
| 753  | 8-9   | population, attributable fractions, Campylobacteriosis case control study, 1998, 1999." | population attributable fractions, <i>Campylobacter</i> case control study, 1998-1999." |
| 753  | 10    | population, attributable  | population attributable   |
| 754  | 6     | population, attributable  | population attributable   |
| 754  | 9     | There's "A," undercooked or pink chicken.   | There's "Ate undercooked or pink chicken."  |
| 754  | 10    | "A" chicken prepared at home  | "Ate chicken prepared at home"  |
| 754  | 14    | "A," undercooked or pink chicken,   | "Ate undercooked or pink chicken",  |
| 754  | 22    | do with this  | do this   |
| 755  | 21    | FoodNet in  | FoodNet population in   |
| 756  | 12    | question  | questions   |
| 757  | 15    | rate  | rates   |
| 763  | 11-12 | on the evidence cause.  | in evidence law.  |
| 763  | 18    | Registrar   | Register  |

|     |       |   |  |
|-----|-------|---|--|
| 763 | 21    | important considering                                 | important, considering                                     |
| 763 | 22    | outside home  | outside the home   |
| 764 | 2-3   | their dollars   | their food dollars   |
| 764 | 11    | rely.   | rely on.   |
| 768 | 16    | limitation is   | limitation of  |
| 768 | 17    | risks   | risk   |
| 768 | 18-19 | fraction."<br>Is it those cases that were             | fraction is that those cases that were                     |
| 768 | 20    | interest even   | interest, even   |
| 768 | 21    | been a cause of the disease,<br>could                 | been the cause of the disease,<br>would                    |
| 768 | 22    | risk thereby  | risk, thereby  |
| 769 | 1     | risk?   | risk".   |
| 769 | 22    | fraction but  | fraction, but  |
| 770 | 3     | ACRIORI   | <i>a priori</i>  |
| 772 | 16    | reduction   | fraction   |
| 774 | 4     | the "A" chicken prepared in                           | the "Ate chicken prepared at a                             |
| 774 | 5     | the restaurant has                                    | restaurant" has  |
| 774 | 6     | 44  | 24   |
| 774 | 9     | says, " 'A' chicken                                   | says, "Ate chicken   |
| 775 | 5     | respond, yes  | respond, "yes  |
| 775 | 6     | home would  | home "would  |
| 775 | 8     | said yes  | said "yes  |
| 775 | 9     | home than   | home" than   |
| 775 | 13    | cases for disease more<br>frequently from exposure to | cases get disease more frequently<br>from exposure than do |
| 776 | 7     | awfully   | awful  |
| 779 | 4     | attachment 29   | attachment 1   |
| 782 | 22    | Schmidt   | Schmid   |
| 783 | 3     | Schmidt, et al in                                     | Schmid, et al Study in                                     |
| 787 | 1     | ill less  | ill persons were less                                      |
| 787 | 7     | set of controls."                                     | set of controls. . . ."                                    |
| 787 | 10    | I said, more  | I said, ". . . more  |
| 787 | 11    | undercooked.  | undercooked."  |
| 788 | 18    | Schmitz study in Debuque                              | Schmid study in Dubuque                                    |
| 789 | 4     | Debuque   | Dubuque  |
| 790 | 10    | here. You're  | here. You  |
| 790 | 16    | as the question.                                      | ask the question.  |
| 790 | 19    | Rodriguez   | Rodrigues  |
| 791 | 5     | Rodriguez   | Rodrigues  |
| 791 | 17    | Rodriguez   | Rodrigues  |
| 791 | 20    | chicken," other than -- nor                           | chicken other than in restaurants<br>nor                   |
| 791 | 21    | kitchen practices. We                                 | kitchen hygiene practices." We                             |
| 792 | 18    | Schmitz   | Schmid   |

|     |     |   |  |
|-----|-----|---|--|
| 792 | 20  | Rodriguez   | Rodrigues  |
| 794 | 3   | epidemial   | endemic  |
| 794 | 22  | contamination   | contaminated   |
| 797 | 4   | CVC   | CDC  |
| 799 | 20  | separating out. This is                               | separating out --- this is                             |
| 800 | 8   | At if   | And if   |
| 802 | 8   | slip of   | flip of  |
| 802 | 18  | indication  | etiologic  |
| 803 | 9   | CVC   | CDC  |
| 803 | 21  | CVC   | CDC  |
| 804 | 13  | Floraquinolone  | fluoroquinolone  |
| 805 | 18  | Predence  | Friedman   |
| 805 | 19  | Predence  | Friedman   |
| 805 | 20  | CVC   | CDC  |
| 806 | 8-9 | Drank untreated water from a lake, river, or stream.  | "Drank untreated water from a lake, river, or stream." |
| 806 | 19  | Floraquinolone  | fluoroquinolone  |
| 808 | 4   | solution  | sewage   |
| 809 | 11  | Norm's  | NARM's   |
| 810 | 14  | proposition trivial                                   | population attributable                                |
| 812 | 2   | know  | known  |
| 812 | 6   | resistant   | resistance   |
| 812 | 18  | talked maybe  | talked about how maybe                                 |
| 817 | 7   | come of   | come out of  |
| 819 | 19  | resistant of chicken                                  | resistant from chicken                                 |
| 821 | 13  | Ciprofloxacin   | ciprofloxacin  |
| 822 | 2   | it says number of                                     | it says "number of                                     |
| 822 | 3   | that indicated -- of                                  | with indicated pathogen" -- of                         |
| 822 | 4   | Ciprofloxacin -- 27; and it says                      | ciprofloxacin -- 37"; and it says                      |
| 822 | 9   | had -- one of the patients                            | had -- among patients                                  |
| 822 | 21  | "Of the   | "Among   |
| 822 | 22  | patients affected with campylobacter                  | patients who had only <i>campylobacter</i>             |
| 823 | 1   | isolate" --   | isolated..."   |
| 823 | 4   | Ciprofloxacin   | ciprofloxacin  |
| 824 | 7   | see. One of these patients, the                       | see. "One of these patients" ...the                    |
| 824 | 8   | -- for 7 days, having -- on                           | -- "for 7 days", having -- "on                         |
| 824 | 9   | resistant. The same isolate                           | resistant..." The "same isolate                        |
| 824 | 10  | 2 days after Ciprofloxacin therapy was initiated. And | 10 days after ciprofloxacin therapy was initiated. A   |
| 824 | 11  | Ciprofloxacin-susceptible species was isolated        | ciprofloxacin-susceptible...species was isolated       |
| 824 | 12  | at admission. That                                    | at admission; that                                     |
| 824 | 13  | four days.  | four days..."  |
| 825 | 10  | Aithromycin   | azithromycin   |

|     |    |                   |                   |
|-----|----|-------------------|-------------------|
| 825 | 11 | Ciprofloxacin     | ciprofloxacin     |
| 825 | 20 | "Recovery         | "Recovered        |
| 826 | 1  | Azithromycin      | azithromycin      |
| 826 | 2  | Azithromycin      | azithromycin      |
| 826 | 3  | Ciprofloxacin     | ciprofloxacin     |
| 830 | 18 | Exhibit 9433.     | Exhibit G-953.    |
| 830 | 21 | Table 1.2?        | Table I.2?        |
| 831 | 4  | I think it's 1.2, | I think it's I.2, |
| 832 | 20 | MR. SPILLER:      | MR. NICHOLAS:     |

**WITNESS:** Louis Cox, Jr.

**DATE TAKEN:** May 6, 2003

| <b>Page</b>  | <b>Line</b> | <b>As Transcribed</b>   | <b>Change To</b>   |
|--------------|-------------|---|--|
| 726          | 4           | Louie Cox, Jr.  | Louis Cox, Jr.   |
| 834          | 22          | Louie Anthony Cox, Jr.  | Louis Anthony Cox, Jr.   |
| 841          | 10          | her   | him  |
| 849          | 22          | checking consumption  | chicken consumption  |
| 850          | 14-15       | what are the causes of the associations.  | what are the causes of the associations?   |
| 853          | 10          | core six.   | course six.  |
| 854          | 9           | none exist.   | none exists.   |
| 856          | 18          | I rush to say   | I blush to say   |
| 866          | 3           | might tackle the approach   | might tackle the problem   |
| 867          | 9           | thought keys  | thought piece  |
| 869          | 3-5         | yet the probability that exactly one person will become ill may be less than the probably that two or more will become ill, right?                        | “yet the probability that exactly one person will become ill may be less than the probably that two or more will become ill, right?”                       |
| 869          | 14-15       | I did say this seems to me to be a very practical, sound approach. I have no remaining concern.   | I did say, “This seems to me to be a very practical, sound approach. I have no remaining concerns.”  |
| 870          | 3-4         | They can be spacial clusters.   | There can be spacial clusters.   |
| 870          | 5           | Let me just say, not necessarily.   | Let me just say: not necessarily.  |
| 870 -<br>871 | 22 -<br>1   | if several people in the same family get sick, it's an outbreak.  | if several people in the same family get sick, is it an outbreak?  |
| 875 -<br>876 | 20 -<br>5   | It's the page on which the first complete sentence is, I mean -- like 10, it -- the study, the model -- it has to make a few baroque assumptions, K being | It's the page on which the first complete sentence is, I mean -- like 10, “It -- the study, the model -- it has to make a few baroque assumptions, K being |

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|           |       | the big one, to get across big data gaps, but it is very explicit about that. So all in all, I think that is a job well done. I want to invite you to critically examine a few assumptions if you share that conclusion. | the big one, to get across big data gaps, but it is very explicit about that. So all in all, I think that is a job well done. I want to invite you to critically examine a few assumptions to see if you share that conclusion.” |
| 877       | 20-21 | the model says risk is equal to big K exposure   | the model says risk is equal to big K times exposure   |
| 878       | 18-19 | where you try to say is this model correct and useful.   | where you try to say, “Is this model correct and useful?”  |
| 878       | 20-21 | saying do its consequences follow from its premises,   | Saying, “Do its consequences follow from its premises?”,   |
| 878       | 22    | empirically valid.   | empirically valid?   |
| 878 - 879 | 22-3  | So these comments are directed at a logical matter, if you would make the big K model work, a lot of little factors, that would be a terrific thing to do.   | So these comments are directed at a <i>logical</i> matter. If you could make the big K model work, a lot of little factors, that would be a terrific thing to do.  |
| 879       | 7     | On that, a somewhat imponderable question.   | Oh, that’s a somewhat imponderable question.   |
| 880       | 19    | Virginia Misen   | Virginiamycin  |
| 883       | 20-21 | And that refers to the number of contracts.  | And that refers to a number of contracts.  |
| 888       | 9-12  | I've -- I don't know. It's not in deadline, I can tell you that. I don't think it was. And again, I tend to have some area of expertise. I think Bayer helped to -- Bayer, with some of the production costs.            | I've -- I don't know. It's not, in my mind, I can tell you that. I don't think it was. And again, it’s outside my area of expertise. I think Bayer helped out -- Bayer, with some of the production costs.                       |
| 890       | 14    | progression models   | regression models  |
| 892       | 1-3   | This is a reference for the rather-than-chicken assumption, per se, portion, not for the restaurant dining portion.  | This is a reference for the “rather-than-chicken consumption, per se” portion, not for the “restaurant dining” portion.  |
| 893       | 17    | And thirdly, the relation that you're referring to is  | And thirdly, if the relation that you're referring to is   |
| 894       | 10-12 | showing up as being significant -- don't be impressed by big odds ratio because of the logarithm scale that goes as low as zero but as high as 70.   | showing up as being significant. Don't be impressed by big odds ratio because of the logarithmic scale that goes as low as zero but as high as 70.   |
| 895       | 1     | I love that data step.   | I love that data set.  |

|           |        |  |  |
|-----------|--------|--|--|
| 895       | 9      | Dr. Angelo's   | Dr. Angulo's   |
| 895       | 11     | Dr. Angelo's   | Dr. Angulo's   |
| 898       | 14-15  | This finding supports not the restaurant dining, but the not chicken per se point.   | This finding supports not the "restaurant dining", but the "not chicken per se" point.   |
| 898       | 17-18  | My point is, why.  | My point is, Why?  |
| 899       | 13-14  | indicates that chicken at home -- I admit -- we haven't gotten down to business yet,   | indicates that chicken at home -- I admit, we haven't gotten down to business yet --   |
| 903       | 14-19  | The Eberhart-Phillips conclusion that you just mentioned uses common causes. Campylobacteriosis is a common disease with a number of common causes, the most important being, at least for campylobacteriosis in New Zealand, the most important being the consumption of undercooked chicken. | The Eberhart-Phillips conclusion that you just mentioned uses "common causes". "Campylobacteriosis is a common disease with a number of common causes, the most important being, [at least for campylobacteriosis in New Zealand], the most important being the consumption of undercooked chicken." |
| 903 - 904 | 22 - 1 | She is drawing a conclusion about causes.  | She is not drawing a conclusion about causes.  |
| 904       | 15-16  | I think there is probably a host of these interactions.  | I think there is probably a host-disease interaction.  |
| 905       | 7-10   | Let's see. There was no statistically significant risk associated with consumption of chicken other than in restaurants, nor with reported domestic kitchen hygiene factor.  | Let's see. "There was no statistically significant risk associated with consumption of chicken other than in restaurants, nor with reported domestic kitchen hygiene factor."  |
| 906       | 13     | logistic progression   | logistic regression  |
| 907       | 14-17  | Absolutely not. If you'll look at table 1 of Effler, you'll see on that on that page 3 of this exhibit you just handed me, from a restaurant there's an association in this model.   | Absolutely not. If you'll look at table 1 of Effler -- you'll see that on page 3 of this exhibit you just handed me -- from a restaurant there's an association in this model.   |
| 908       | 15     | math odds ratio  | matched odds ratio   |
| 910       | 11-14  | I state that he used a particular model conditional logistic progression without reporting the standard model diagnostics and tests that would roughly correspond to what I just said.   | I state that he used a particular model --conditional logistic regression -- without reporting the standard model diagnostics and tests that would roughly correspond to what I just said.   |
| 910       | 16     | how variable testing was done.   | how variable selection was   |

|     |    |                           |                             |
|-----|----|---------------------------|-----------------------------|
|     |    |                           | done.                       |
| 912 | 19 | No, it's seem to support. | No, it's "seem to support". |

**WITNESS:** Louis Cox, Jr.

**DATE TAKEN:** May 7, 2003

| Page | Line  | As Transcribed   | Change To  |
|------|-------|--|--|
| 925  | 3     | Louie Cox, Jr.   | Louis Cox, Jr.   |
| 925  | 6     | LOUIE COX, JR.   | LOUIS COX, JR.   |
| 930  | 9     | Michael Bond   | Michael Vaughn   |
| 931  | 1     | Dr. DeGrowth.  | Dr. DeGroot.   |
| 931  | 19    | Dr. DeGrowth   | Dr. DeGroot  |
| 932  | 14    | Dr. DeGrowth   | Dr. DeGroot  |
| 937  | 5, 10 | Rodriguez  | Rodrigues  |
| 941  | 20    | Louie Cox, Jr.   | Louis Cox, Jr.   |
| 946  | 1     | reduction stage.   | production stage.  |
| 951  | 16    | Of course, minor effect demonstrates.  | Of course: "minor effect demonstrate(s)".  |
| 955  | 4     | I continued through, for example -- oh, here's where the log 10 comes in. For example, a reduction of three log 10 colony forming units per chicken.   | I continued through, "For example...". Oh, here's where the log 10 comes in: "For example, a reduction of three log 10 colony forming units per chicken..."  |
| 956  | 11    | What I show is not a quote but which is pertinent and reflects the point there is that the effect of such a decrease in the number -- it's a pretty large decrease in the number of campylobacter would not have been detected by the -- what he refers to as "qualitative methods," meaning the prevalence metric.  | What I show is not a quote, but -- which is pertinent and reflects the point there -- is that the effect of such a decrease in the number (it's a pretty large decrease in the number of campylobacters) would not have been detected by the -- what he refers to as "qualitative methods," meaning the prevalence metric.   |
| 962  | 4     | represents using   | represents, using  |
| 966  | 11    | several things on here   | several things going on here   |
| 967  | 6     | In all of the cases, if I'm not referring to figures, specialized to the context such as 7(a) and 7(b) and something that I pull out, or if a reference, for example, a number is given, reference 17, that's not pertinent to the content, I would not feel obliged to repeat those typographical marks in the quoted section -- for example, in a journal article. | In all of the cases, if I'm not referring to figures (specialized to the context, such as 7(a) and 7(b), and something that I pull out); or if a reference -- for example, a number is given, reference 17, that's not pertinent to the content - - I would not feel obliged to repeat those typographical marks in the quoted section, for example, in a journal article. |



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| 968 | 8  | I think that correcting the punctuation and putting in the S -- I think that's fair. The how to deal with the sentence break around the deleted figure reference, in light of our long discussion, I question in my own mind whether it would have been useful to have quoted the entire thing either though that would be duplicating material already in there. | I think that correcting the punctuation and putting in the S, I think that's fair. The how to deal with the sentence break around the deleted figure reference... In light of our long discussion, I question in my own mind whether it would have been useful to have quoted the entire thing, either, though that would be duplicating material already in there. |
| 969 | 11 | looks to me that this   | looks to me like this   |
| 970 | 11 | as a form for   | as a farm-to-fork   |
| 971 | 1  | and that Rosenquist demonstrates is not linear is   | and that Rosenquist demonstrates is not linear -- is  |
| 971 | 4  | microbial lode  | microbial load  |
| 971 | 10 | Prevalence says not how many microbes is this chicken carrying; prevalence says what fraction of flocks in this case have at least some campylobacter present.  | Prevalence says not, "How many microbes is this chicken carrying?" Prevalence says, "What fraction of flocks in this case have at least some campylobacter present?"  |
| 972 | 16 | microbial load has held constant  | microbial load is held constant   |
| 972 | 18 | microbial load, such as all the situations I'm looking at where Enrofloxacin use is contemplated.   | microbial load... such as all the situations I'm looking at, where Enrofloxacin use is contemplated.  |
| 973 | 21 | So for you to say that CVM incorporates an important component is to leave out everything important which is in simulation runs where microbial load doesn't change, for example, because there's no manipulation of Enrofloxacin use.  | So for you to say that "CVM incorporates an important component" is to leave out everything important which is in simulation runs where microbial load doesn't change -- for example, because there's no manipulation of Enrofloxacin use.  |
| 975 | 21 | A An approximately linear relationship for these simulations. The reason I'm saying that is it's not a general relationship. It's a relationship conditioned on what we just talked about, which is holding microbial load constant.  | A An approximately linear relationship for <i>these</i> simulations. The reason I'm saying that is, it's not a <i>general</i> relationship. It's a relationship conditioned on what we just talked about -- which is holding microbial load constant.   |
| 976 | 8  | Actually, not necessarily, but you're falling into I think just the perhaps confusion that I was trying to clarify which is these are not   | Actually, not necessarily. But you're falling into I think just the, perhaps, confusion that I was trying to clarify, which is: these   |

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|     |            | <p>general relationships. These are plots of perhaps 8 different simulation run outputs.</p> <p>To that, you're trying to attach a general rule which is that human illness is proportional to flock prevalence. I'm telling you that general rule is an incorrect generalization because in general, microbial loads are not held constant as they are in these simulations.</p> | <p>are <i>not</i> general relationships. These are plots of perhaps 8 different simulation run outputs.</p> <p>To that, you're trying to attach a general rule, which is that human illness is proportional to flock prevalence. I'm telling you: that general rule is an incorrect generalization because, in general, microbial loads are <i>not</i> held constant as they are in these simulations.</p> |
| 980 | 1          | I was hung up on which of the many assumptions, some explicit, some subsequently described, by CVM as being implicit but not explicitly stated you were thinking of.  | I was hung up on which of the many assumptions -- some explicit, some subsequently described, by CVM, as being implicit but not explicitly stated -- you were thinking of.   |
| 981 | 2          | Rodriguez   | Rodrigues  |
| 982 | 16, 16, 21 | Rodriguez   | Rodrigues  |
| 982 | 20         | Almost. The demonstrably is only partially covered. I'd say for Rodriguez it's suggested.   | Almost. The "demonstrably" is only partly covered. I'd say for Rodrigues, it's suggested.  |
| 983 | 3, 4, 19   | Rodriguez   | Rodrigues  |
| 984 | 13, 14, 20 | Rodriguez   | Rodrigues  |
| 984 | 14         | I cite Rodriguez to support the idea travel abroad and consumption of chicken in a restaurant are associated with being a cause,  | I cite Rodriguesz to support the idea that travel abroad and consumption of chicken in a restaurant are associated with being a case,  |
| 985 | 1          | Well, again, what Rodriguez says, being careful to exactly quote his words, in the abstract on page 1, fourth line, sentence starting at the end of that line, where travel, he says two things -- two main things. Travel abroad and consumption of chicken in a restaurant were statistically associated with being a cause -- so yes, he talks about                           | Well, again, what Rodriguez says (being careful to exactly quote his words), in the abstract on page 1, fourth line, sentence starting at the end of that line, where travel - - he says two things -- two main things: Travel abroad, and consumption of chicken in a restaurant, were statistically associated with being a cause. So  |

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|      |             | chicken in a restaurant.   | yes, he talks about chicken in a restaurant.  |
| 985  | 1           | Rodriguez  | Rodrigues   |
| 986  | 1           | And as I said, I cited myself and my own causal analysis for the demonstrably part   | And as I said, I cited myself and my own causal analysis for the "demonstrably" part  |
| 986  | 6, 7, 8, 17 | Rodriguez  | Rodrigues   |
| 987  | 18          | Rodriguez  | Rodrigues   |
| 992  | 6           | This article doesn't discuss or this abstract doesn't discuss whether the design is prospective, saying if you have poor kitchen hygiene are you more likely to get campylobacteriosis or whether it's retrospective, meaning if you got campylobacteriosis, it's more likely that you had poor kitchen hygiene. | This article doesn't discuss (or this abstract doesn't discuss) whether the design is <i>prospective</i> -- saying if you have poor kitchen hygiene, are you more likely to get campylobacteriosis? -- or whether it's <i>retrospective</i> , meaning: if you got campylobacteriosis, it's more likely that you had poor kitchen hygiene. |
| 992  | 15          | This may be showing if you ask people who are sick, hey, did you wash your hands, more of them will say no, which is the point -- the distinction I was aiming at before.  | This may be showing, if you ask people who are sick, "Hey, did you wash your hands?", more of them will say no -- which is the point, the distinction, I was aiming at before.  |
| 993  | 10          | What it could be showing is that people who are asked, after they become cases, did you wash your cutting board, are more likely to respond no.  | What it could be showing is that people who are asked, after they become cases, "Did you wash your cutting board?" are more likely to respond "No".   |
| 994  | 15          | I don't think that's correct, but -- and the reason is what exactly does "unattributed" mean here. you know, is it unattributed because there was no evidence that this was the source?  | I don't think that's correct. But -- and the reason is, what exactly does "unattributed" mean here? You know, is it "unattributed" because there was no evidence that this was the source?  |
| 999  | 4           | I didn't say which I interpreted. Which I know, as I sit here, interpret as an average, yes, per capita.   | I didn't say "which I interpreted". Which I now, as I sit here, interpret as an average -- yes, per capita.   |
| 999  | 17          | NOO page.  | NOOH.   |
| 1000 | 1           | You mean the risk assessment itself or the CVM assessment?   | You mean the risk assessment itself or what CVM said about its risk assessment?   |
| 1000 | 6           | represents their use of what they  | represents their use, i.e., what  |

|      |    | meant about it.  | they meant about it.   |
|------|----|--|--|
| 1001 | 13 | No. I'm not looking for those words. I am looking for these words: human health impact, lamda, is equal to some constant, k-res, times the pounds of chicken consumed with Fluoroquinolone-resistant campylobacter. And my point is that this is describing risks to a typical on average a representative consumer. | No. I'm not looking for those words. I am looking for these words: human health impact, lambda, is equal to some constant, k-res, times the pounds of chicken consumed with Fluoroquinolone-resistant campylobacter. And my point is that this is describing risks to a typical or average or representative consumer. |
| 1001 | 20 | I know that's been stated and, you know, what's not here is what is the distribution of exposures for different people.  | I know that's been stated. And, you know, what's <i>not</i> here is: What is the distribution of exposures for different people?   |
| 1003 | 13 | Yes. For example, you could say this is a, quote, hypothetical. It wouldn't have to be that somebody actually said that --   | Yes. For example, you could say this is a, quote, "hypothetical". It wouldn't have to be that somebody actually said that --   |
| 1006 | 11 | And that does not establish a relation between them, again, quoting from all the written discussion on this, in any meaningful or useful sense.  | And that does not "establish" a "relation" between them, again quoting from all the written discussion on this, in any meaningful or useful sense.   |
| 1006 | 21 | I believe that the examples are -- I attempt to suggest that the aggregate -- I'm sorry -- the ratio of aggregate level of campylobacteriosis cases to the aggregate level of chicken consumption has not been shown to have any stronger causal connection than other ratios, including manifestly ridiculous ones. | I believe that the examples are. I attempt to suggest that the aggregate...I'm sorry. The ratio of aggregate level of campylobacteriosis cases to the aggregate level of chicken consumption has not been shown to have any stronger <i>causal</i> connection than other ratios, including manifestly ridiculous ones. |
| 1008 | 4  | A When I reviewed this model in 1999, was I not -- when I reviewed the risk assessment I certainly read what was written about the design.   | A When I reviewed this model in 1999, was I not? When I reviewed the risk assessment I certainly read what was written about the design.   |
| 1010 | 10 | As you will -- I'm sorry -- and you will notice that the big assumption is that the incidence of bad outcomes more formally in response that we don't want is proportional to the volume of  | "As you will" -- I'm sorry. "And you will notice that the big assumption is that the incidence of bad outcomes [more formally, of <i>response</i> ] that we don't want is proportional to the volume of  |



|      |           |   |   |
|------|-----------|---|---|
|      |           | outgoing chicken informally the exposure, or something proportional to exposure.  | outgoing chicken [informally the <i>exposure</i> , or something proportional to exposure].  |
|      |           | Right. It's exposure and undesirable or bad effect, not dose response.  | Right. It's "exposure" and "undesirable (or bad) effect", not "dose" and "response".  |
| 1014 | 14        | I spoke informally of munging together different parameters, said this was something that needed to be checked out.   | I spoke informally of "munging together different parameters" and said this was something that needed to be checked out.  |
| 1015 | 3         | First thing is to be correct.   | The first thing is to be correct.   |
| 1015 | 10        | making it open and inspectable and documenting the assumptions is all good things.  | making it open and inspectable and documenting the assumptions are all good things.   |
| 1024 | 3         | When you say your model, this is an early version.  | When you say "your model", this is an early version.  |
| 1024 | 13        | It depends if you're referring to Cox 2002, then it was the 2002 model.   | It depends. If you're referring to Cox 2002, then it was the 2002 model.  |
| 1028 | 11        | my statement that sensitivity analysis provides partial solution to the problem of unknown variable dose response relations.  | my statement that "Sensitivity analysis provides a partial solution to the problem of unknown and variable dose response relations."  |
| 1031 | 1         | What I was not relying on as I have clearly written is any assumption that there can't be any risk below 500 CFUs. And as I've written in Exhibit B-1629 on page 36, any dose response relation with these qualitative features that are discussed tends to produce similar expected number of CB cases from given population frequency distribution microbial loads. | What I was <i>not</i> relying on, as I have clearly written, is any assumption that there can't be any risk below 500 CFUs. And, as I've written in Exhibit B-1629 on page 36, <i>any</i> dose response relation with these qualitative features (that are discussed) tends to produce similar expected number of CP cases from a given population frequency distribution of microbial loads. |
| 1034 | 3, 15, 22 | Tunis   | Teunis  |
| 1035 | 14, 22    | Tunis   | Teunis  |
| 1037 | 1         | Tunis   | Teunis  |
| 1039 | 11, 14    | Tunis   | Teunis  |
| 1040 | 17        | Tunis   | Teunis  |
| 1042 | 13,       | Tunis   | Teunis  |

|      |           |  |   |
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|      | 16        |  |   |
| 1042 | 18        | You know, I could find myself with a range of data.  | You know, I confined myself to the range of the data.   |
| 1043 | 14,<br>18 | Tunis  | Teunis  |
| 1044 | 7         | Tunis  | Teunis  |
| 1044 | 12        | <p>My model states -- or my description and discussion of exactly this issue in my model states that risks are low or zero. They don't have to be zero, they can be low for sufficiently small doses, e.g., less than 500 CFUs, doesn't have to be 500 CFUs, and illness probability increases rapidly as a function of dose reaching an approximate plateau -- this is now describing why I deal with this model in my model -- it reaches an approximate plateau of about .2 for CFU levels of about a thousand to 10,000 CFUs.</p> <p>What I've said is by doing sensitivity analyses, I've found that any dose response model that captures the rough qualitative features of the data will suffice.</p> | <p>Well, no. My model states (or my description and discussion of exactly this issue in my model states) that risks are low or zero. They don't have to be zero. They can be low for sufficiently small doses, e.g., less than 500 CFUs -- it doesn't have to be 500 CFUs. And illness probability increases rapidly as a function of dose, reaching an approximate plateau. This is now describing how I deal with this model in my model -- it reaches an approximate plateau of about .2 for CFU levels of about a thousand to 10,000 CFUs.</p> <p>What I've said is: by doing sensitivity analyses, I've found that <i>any</i> dose response model that captures the rough qualitative features of the data will suffice.</p> |
| 1045 | 13        | Popkin   | Popken  |
| 1046 | 1         | Tunis  | Teunis  |
| 1047 | 11        | <p>If you look at those data, you'll see that assuming that there's zero response to zero dose, the pattern as far as we know is that not much happens and I don't believe that there are data for humans below about 500 CFUs. Well, not in this experiment.</p> <p>Basically, not much happens until you get up to a few hundred CFUs, then about 20 percent of people get sick. So I think that these data from one feeding study -- it's hard to know what to make of them but they're consistent with the idea that there's</p>   | <p>If you look at those data, you'll see that, assuming that there's zero response to zero dose, the pattern as far as we know is that not much happens (and I don't believe that there are data for humans below about 500 CFUs -- well, not in this experiment) -- basically, not much happens until you get up to a few hundred CFUs. Then about 20 percent of people get sick. So, I think that these data from one feeding study -- it's hard to know what to make of them, but they're consistent with the idea that there's a higher</p>   |

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|      |    | a higher response probability when you have several hundred, several thousand CFUs. And we don't really know what happens in the low dose range.   | response probability when you have several hundred, several thousand CFUs. And we don't really know what happens in the low-dose range.  |
| 1048 | 12 | Tunis  | Teunis   |
| 1051 | 4  | and there has subsequently been peer review to published.  | and that has subsequently been peer reviewed and published.  |
| 1052 | 5  | are extremely robust, the assumptions.   | are extremely robust to the assumptions.   |
| 1053 | 21 | a bilinear probability   | a binomial probability   |
| 1054 | 2  | For the next one down, another bilinear distribution,  | For the next one down, another binomial distribution,  |
| 1054 | 4  | For the surface microbial load which starts to get exciting from a cause and effect point of view, as specified, a triangular distribution for the lot of 10 of the values.  | For the surface microbial load (which starts to get exciting from a cause-and-effect point of view), as specified, a triangular distribution for the log of 10 of the values.  |
| 1055 | 11 | And there's a substantial framework that these piece by piece steps get into to justify that dual role and that is the framework outlined in the exhibit that I just referred to, the B-1020 -- in my book.  | And there's a substantial framework that these piece-by-piece steps fit into to justify that dual role. And that is the framework outlined in the exhibit that I just referred to, the B-1020 - - in my book.  |
| 1056 | 22 | In this role of the table, yes.  | In this row of the table, yes.   |
| 1060 | 4  | This is a matter of what the operational definition of the numbers mean. My operational, I mean what measurement procedures are we using.  | This is a matter of the <i>operational definition</i> of what the numbers mean. By "operational" I mean, what measurement procedures are we using?   |
| 1063 | 10 | The point there is that mean variance for each step in a process where a number of factors are being multiplied is sufficient when there are a large number of steps, as there are here, fully characterize the distribution, the meaning of the variance for the overall process. | The point there is that the mean and variance for each step in a process where a number of factors are being multiplied is sufficient (when there are a large number of steps, as there are here) to fully characterize the distribution, the mean and variance for the overall process. |
| 1063 | 22 | I believe that reads like a geometric medium   | I believe that reads like a geometric median   |
| 1066 | 10 | For example, this would be incorrect if the population had a certain distribution,   | For example, this would be incorrect if the population had a Cauchy distribution,  |



|      |    |  |  |
|------|----|--|--|
| 1068 | 4  | The sample limit theorem that I referred to deals with the composition of multiple multiplicative steps.   | The specific central limit theorem that I referred to deals with the composition of multiple multiplicative steps.   |
| 1069 | 3  | It's only partially derived but there's a much simpler argument to getting there that's much more data driven.   | It's only partially derived. But there's a much simpler argument for getting there that's much more data driven.   |
| 1070 | 21 | No, I didn't rely on it because you might be able to remove one or two points and change the answer in something that only has 7 data points. What I relied on was the underlying data, which is a lot richer but this is the simplest way of showing the results.   | No, I didn't rely on it, because you might be able to remove one or two points and change the answer, in something that only has 7 data points. What I relied on was the underlying data, which is a lot richer. But this is the simplest way of showing the results.  |
| 1071 | 5  | You picked the regression equation for this?   | Who picked the regression equation for this?   |
| 1071 | 6  | The statistics package that I was using in the upper not clearly legible margin of the picture.  | The statistics package that I was using (in the upper, not clearly legible, margin of the picture.)  |
| 1072 | 7  | What I'm saying is if you take the simplest possible look at the data, you'll see it doesn't look anything like straight line sloping upward to the right  | What I'm saying is: If you take the simplest possible look at the data, you'll see it doesn't look anything like a straight line sloping upward to the right.  |
| 1073 | 10 | I don't think I used the jargon exploratory data analysis. I think I have indicated in multiple places that the simplest way of looking at the data that the hypothesis, that it's a cluster around a straight line leaning from the lower left corner upwards has no relation to the real data even when you look at it in the simplest possible way. | I don't think I used the jargon "exploratory data analysis". I think I have indicated in multiple places that with the simplest way of looking at the data, that the hypothesis (that it's a cluster around a straight line leaning from the lower left corner upwards) has no relation to the real data, even when you look at it in the simplest possible way. |
| 1074 | 11 | Well, this testimony was written with hyperlink in it and they were very close based on hyperlink but I'm not sure how close they are in terms of pages.   | Well, this testimony was written with hyperlinks in it, and they were very close based on hyperlinks. But I'm not sure how close they are in terms of pages.   |
| 1076 | 11 | aggression   | regression   |
| 1079 | 6  | little slow to go along with either.   | little loathe to go along with "either".   |
| 1079 | 14 | one forces -- use  | one forces it -- use   |

|      |       |                                   |                                    |
|------|-------|-----------------------------------|------------------------------------|
| 1080 | 6     | is you should                     | is, you should                     |
| 1082 | 14-15 | mark for exhibit                  | mark for an exhibit                |
| 1085 | 11    | FDA.                              | USDA.                              |
| 1089 | 3     | the human health risk, is         | that human health risk is          |
| 1090 | 10    | it in a                           | it as a                            |
| 1092 | 15    | predictable                       | predicting                         |
| 1093 | 11    | totally private?                  | totally in private?                |
| 1093 | 13    | about we should                   | about how we should                |
| 1095 | 12    | Rodriguez                         | Rodrigues                          |
| 1095 | 15    | raw data and                      | raw data, and                      |
| 1095 | 16    | that data as                      | that data, as                      |
| 1098 | 2     | being not clear.                  | not being clear.                   |
| 1098 | 14    | Rodriguez                         | Rodrigues                          |
| 1103 | 10    | controlled                        | control                            |
| 1105 | 12    | Erisycolitis                      | air sacculitis                     |
| 1105 | 12    | Erisycolitis                      | air sacculitis                     |
| 1106 | 4     | Erisycolitis                      | air sacculitis                     |
| 1108 | 3, 21 | Rodriguez                         | Rodrigues                          |
| 1108 | 5     | are saying it doesn't             | are saying: "it doesn't            |
| 1108 | 6     | it be, why didn't things          | it be? Why didn't things           |
| 1108 | 7     | drug.                             | drug?"                             |
| 1113 | 2     | your                              | you're                             |
| 1114 | 20    | called eight chick.               | called "ate" chick.                |
| 1114 | 21    | Eight chick,                      | "Ate chick",                       |
| 1116 | 17    | classification, vis farm, you got | classification "vis farm", you got |

DATED this the \_\_\_\_ day of \_\_\_\_\_, 2003.

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Daniel J. Davidson  
Administrative Law Judge

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**MCDERMOTT, WILL & EMERY**

June 6, 2003

**VIA HAND DELIVERY**

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

Re: Enrofloxacin for Poultry: Withdrawal of Approval of  
New Animal Drug Application  
NADA 140-828; FDA Docket: 00N-1571

Dear Sir/Madam:

Enclosed for filing please find an original and two copies of Respondent Bayer Corporation's Proposed Corrections in the Transcript of Oral Testimony.

Please call with any questions.

Sincerely,



Gregory A. Krauss

GAK:jeh

Enclosures

cc: Nadine Steinberg, Esquire (w/enclosure)  
Kent McClure, Esquire (w/enclosure)

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