March 17, 2003

Dr. Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Docket No. 02N-0291

Dear Dr. Woodcock:

Please allow me to supplement my submissions to you dated January 30, 2003 and February 25, 2003.

This submission provides you with details on "Findings of Facts and Law" by Court of Appeals for the Seventh Circuit in two earlier opinions issued in 1999 and 2001. The third appeal (03-1120) based upon U.S. Supreme Court's decision in Neder v. United States, 527 U.S. 1(1999) is still pending.

While we do not agree with everything in their findings or their conclusions, we do believe their findings of facts and application of law will be helpful in understanding this complex and lengthy ordeal.

We believe FDA must give Bhutanis an opportunity for a hearing before the administrative law judge. Any decision you make here, if applied fairly to all of the pharmaceutical industry, will impact almost everyone involved in manufacturing or marketing pharmaceuticals in the United States.

Thank you.

Sincerely,

Baldev R. Bhutani, Ph.D.
Inmate No. 05458-424
P.O. Box 1000
Duluth, MN 55814

cc Docket Management Branch
HFA 305; Room 1061
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5630 Fishers Lane
Rockville, MD 20857

02N-0291 SUP 2

Findings of Facts and Law by the Court of Appeals for the Seventh Circuit in *United States v. Baldev R. Bhutani* et al.

The Court of Appeals for the Seventh Circuit has issued two opinions and the opinion on third appeal is pending:

I. *United States v. Bhutani,* 175 F. 3d 572 (7th Cir. 1999) Appeal No. 98-1154;

II. *United States v. Bhutani,* 266 F. 3d 661 (7th Cir. 2001) Appeal No. 00-1523 and 00-2679 and

III. *United States v. Bhutani,* Appeal No. 03-1120

If we were to carefully review two appellate decisions, we will find that the following facts have evolved.

1. Issue of criminal law relating to affirmative duty of the FDA and DOJ to disclose exculpatory evidence on issue of guilt or punishment.
2. Government's affirmative statements that it never argued and did not challenge the safety or efficacy of the drugs, ...it only argued that drugs did not meet CGMP regulations.
3. Loss to consumers based on gain from consumers receiving mislabeled drugs was not an issue as defendants were found non guilty on Counts 2 and 5 of the indictment where mislabeling was alleged.
4. ALRA's responsibility on establishing and maintaining (accurate) drug manufacturing batch records was a factual as well as legal issue.
5. Loss to consumers was based on gain on consumers receiving drugs that were not manufactured according to FDA

regulations and not because the drugs were not safe or effective.

6. Jury instructions: Appellants and the Government agree that Jury received no instructions on:
   a. How defendants violated CGMP or FDA regulations and/or
   b. If these violations were material as the Government now concedes they did not effect the safety or efficacy of the drugs.

Bhutani argues that, under these circumstances, the verdict and the sentence is flawed. Hopefully Judges familiar with pharmaceuticals and FDA law will now understand the defendant's arguments in its pending appeal and grant relief as law and justice require.

Lets now carefully review the two appellate decisions:

1. Issue of criminal law relating to affirmative duty of the FDA and DOJ to disclose exculpatory evidence on issue of guilt or punishment.

The appellate Judges described the Government's Brady obligations in criminal law 700(2.1) and 700(7) as follows:

> **"3. Criminal Law 700(2.1)**
>
> Government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant and is material to either the issue of guilt or punishment."
>
> 175 F. 3d 572

"9. Criminal Law 700(7)

While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of Brady material will be imputed to the prosecution."

175 F. 3d 573

Both the Government's prosecutors and the FDA, the Government's agency involved in investigation and consultation with the prosecution, had affirmative duty. In this case more than ten FDA employees testified at the trial.

On page 577 of the opinion in 175 F. 3d 577 appellate Judges explained the Brady obligation briefly and listed the case law in support of this affirmative duty. The court said:

"[9] While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of Brady material will be imputed to the prosecution. See *United States v. Wood,* 57 F.3d 733, 737 (9th Cir. 1995); *United States v. Anderson,* 36 F.Supp.2d 1264, 1267 (D.Kan.1998). "The government cannot with its right hand say it has nothing while its left hand holds what is of value." *Wood,* 57 F.3d at 737."

175 F.3d 577

This obligation applies equally to all of the favorable evidence or material to either the issue of guilt or punishment.

The appellate court however mischaracterized the stability data in FDA possession since 1985 as new. Defendants were indicted in 1994 and the trial did not start until December 1995. The stability data was therefore not new. Defendants did not find out that it existed and that FDA had it all along until United States Pharmacopoeia (USP) disclosed it and its favorable nature until after the trial had ended in Feb. 1996.

2. Government's affirmative statements that it never argued and did not challenge the safety or efficacy of the drugs, ...it only argued that drugs did not meet CGMP regulations:

There was a major disagreement between the Defendants and the Government on the theory of alleged crimes. The appellate court reviewed the trial testimony and declared:

> "After reviewing the trail transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit or close to unfit."
>
> 175 F.3d 578

Once again, defendants argued that this finding by the court was in error. The appellate court in a second opinion said the following:

"A second read of the trail transcript reveals that the government's position at trial and on appeal has been consistent. The government did not show at trial that the Lactulose was outside accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected. The medical efficacy of the Lactulose was only mentioned by the government to explain the significance of expiration dating to the jury."

The court supported it's conclusion by further stating that:

"Neither Dr. Hicks nor any other government witness, ever testified that the Lactulose in question was ineffective."

175 F.3d 578

and

"The government argued that the defendants put the public's safety at risk by supplying adulterated products, not necessarily ineffective ones."

175 F.3d 579

The court, then describing the stability data as new data, concluded that defendants were found guilty of adulterating Lactulose by the addition of sodium hydroxide and we need not find if the new stability data was exculpatory or favorable to the issue of guilt. On page 579 of the opinion it said:

> "Therefore, while the new data could show that the Lactulose had not degraded to the point of making it unsafe, the jury nonetheless found that the drug was adulterated by the addition of sodium hydroxide."
>
> 175 F.3d 579

They further supported this theory by analyzing the jury instructions on adulteration, governments and defendants opposing arguments on what occurred at the trial. The court said:

> "The (district) judge instructed the jury that the drug could have been adulterated in one of three ways. First, it could have been produced in a way that did not conform with the good manufacturing practices. Second, it could have decomposed to such a point that it no longer met applicable testing specifications. Third, the defendants could have added sodium hydroxide to it. The jury only had to find that any one of those three events occurred for the drug to be adulterated. The same is true for count 6."
>
> 175 F.3d 579

and

"The defendants.....specifically, contend that at trial the government said that the defendants had added sodium hydroxide to decomposed Lactulose in hopes of concealing its medical ineffectiveness, but on appeal admitted that the Lactulose was medically effective by iterating that it was within the accepted pH range before the addition of sodium hydroxide. On remand, the district court agreed with the defendants that the government had changed its theory."

266 F.3d 663

and

"The government counters that its focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar to the 1988 lots so that they could bear the same expiration date and be sold. The government's position was that the defendants masked the fact that the Lactulose was degrading and past its expiration date in order to make money."

266 F.3d 663

The appellate court then briefly summarized what District Judge Grady's 1997 opinion in WL 811689 said by the following and we quote:

"The district court agreed with the defendants. The court stated that the government's prevailing theme throughout the case was the defendants' blatant disregard for public safety by shipping adulterated drugs into the marketplace just so

> they could not lose any profits by discarding the old, decomposed Lactulose lots. The court went on to say that since this new stability data showed that Lactulose was still effective at a lower pH level than the government represented at trial, the data tends to show that the defendants would have less of a reason to be nervous about a pH level of 4.6, and, therefore, had no need to spike the product to raise its pH level. Thus, the court determined that the government's suppression of this new stability data "seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4, and 6." *United States v. Bhutani,* 1997 WL 811689 at *14 (N.D.Ill. 1997). In addition, the court found that all of the counts of conviction were so entwined in the government's profit motive theory that it ordered a new trial for all defendants on all of their convictions, even those unrelated to the Lactulose charges."
>
> 175 F.3d 576

The appellate court, even after acknowledging that district courts granting of a new trial was deferential, concluded that they must reverse his decision when it said:

> "The district court's decision relies heavily on the idea that the government portrayed the defendants as profit-hungry monsters who were willing to put the public's safety at risk in order to make a buck by putting ineffective drugs on the market. The court said that the government argued that the defendants spiked their Lactulose lots because they wanted to mask the fact that the product would soon be unfit for use. *Bhutani,* 1997 WL 811689 at *12 (N.D.ILL.1997). Thus, the district court

concluded that the new evidence undermines the government's profit-motive theory and the jury could very well have reached a different conclusion had it known of the new effective range."

175 F.3d 578

The appellate court concluded by stating that:

"We agree with the government"

266 F.3d 664

The appellate court for the second time confirmed that the issue at the trial, was not safety or efficacy of the drugs but in the manner they were adulterated ie drugs did not comply with current Good Manufacturing Practices (CGMP).

3. Loss to consumers based on gain from consumer's receiving mislabeled drugs was not an issue as defendants were found guilty on Counts 2 and 5 of the indictment where mislabeling was alleged.

The appellate court described the governments theory both during trial and at the sentencing hearings as follows:

"The government counters that its focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar to the 1988 lots so that they could bear the same expiration date and be sold. The government's position was that the defendants masked the fact that the Lactulose was degrading and past its expiration date in order to make money."

266 F.3d 663

Counts 2 and 5 of the indictment charged defendants with marketing Lactulose batches under false expiration date. However, the court failed to state that all defendants were found not guilty on these counts. Therefore, this statement even if true, was moot and did not apply to loss to consumers from mislabeling of these two batches of Lactulose.

4. ALRA's responsibility on establishing and maintaining (accurate) drug manufacturing batch records was a factual as well as legal issue.

The appellate court reviewed the charges in Count 4 of the indictment extensively. The alleged crime here involved establishing and maintaining (accurate) records. The court said:

> "The defendants argue that Count Four, which charged that the defendants "[o]n or about August 12, 1988 ... with intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the generic drug product, Lactulose Syrup USP" in violation of 21 U.S.C. § 331(e), along with the correlating conspiracy charge in Count One, failed to state a crime for which they could be convicted."
>
> 266 F.3d 665

The appellate court then described the facts on this issue as follows:

> "There was a gap between 1984 and 1990 where under the plain statutory language the failure

> to establish or maintain records under § 355(k) was not subject to criminal penalties. This time gap is of import to this case; the defendants' conduct charged under § 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct. As noted, the defendants argue that under the plain language of the statute they cannot be penalized for failing to establish and maintain records."
>
> 266 F.3d 665

It then summarized the governments argument on this issue as follows:

> "The government argues that the elimination of the penalty was a scrivener's snafu, and criticizes the defendants hyper-technical and illogical reading of the statute."
>
> 266 F.3d 666

The appellate court then discussed the law on failure to establish and maintain (accurate) drug manufacturing batch records as follows:

> "Generally, courts strictly construe criminal statutes against the government and in the defendant's favor. See *Barrett v. United States,* 423 U.S. 212, 218, 96 S.Ct. 498, 46 L.Ed.2d 450 (1976); 3 NORMAN J. SINGER, SUTHERLAND STATUTORY CONSTRUCTION § 59.03 (5th ed. 1992)."
>
> 266 F.3d 668

and

"[4] While the plain language of the FDCA clearly prohibited the failure to establish or maintain records, criminal penalties were not clearly imposed."

1d. at 668

and

"Strictly reading and applying the FDCA as it was at the time of the offense in question would put the plain language at odds with the statute's purpose and intent. There is no indication in the legislative history that in amending the FDCA Congress intended to eliminate the penalties."

1d. at 668

The court then denied defendants the requested relief by concluding that:

"Therefore, we hold that the failure to establish or maintain records under § 355(k) was subject to criminal penalties despite the typographical error in §331(e) between 1984 and 1990."

266 F.3d 668

5. Loss to consumers was based on gain on consumers receiving drugs that were not manufactured according to FDA regulations and not because the drugs were not safe or effective.

After establishing that the violative drugs were not in regulatory compliance, the appellate court established law as follows:

"9. Sentencing and Punishment⇒736
Defendant's gain from sale of mislabeled and

> adulterated drugs was appropriate measure of loss attributed to fraud, for purposes of calculating base offense level for offense involving fraud; consumers bar-gained for FDA-approved drugs that were in compliance with the law but got drugs that had been mislabeled and adulterated. U.S.S.G. § 2F1.1, 18 U.S.C.A.
>
> 266 F.3d 662, 663

> Appellants, defendants have argued that as there was no issue on drugs safety or efficacy; drugs performed as expected and therefore consumers suffered no loss.

The court summarized the government's argument on loss to consumers as follows:

> "The government in our case argues that there was loss to consumers because consumers paid for FDA-approved drugs, but received drugs that were not manufactured according to the FDCA and FDA regulations; therefore, the government argues that the amount of the defendant's gain is an appropriate measure of loss."
>
> 266 F.3d 669

During sentencing hearings held in January - June 2000, District Judge John F. Grady found:

> "I find that there was an issue as to whether these drugs had been properly manufactured.
>
> I'm not saying that there was an issue as to whether they would be injurious to health or necessarily even an issue as to whether they would be effective for their pharmaceutical purpose. What I find, rather, is that there was an issue as to whether they had been manufactured in such a way that the consumers of those drugs

were being sold something other than what they thought they were buying.

I don't think that any consumer of any of those drugs would have bought those drugs had the consumer known what had happened to them."

266 F.3d 669

On appeal, the appellate court held that while they do not agree with District Judge's reasoning, the court will however adopt the loss value because:

"The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather, the district court was justified in determining that there was a loss because consumers did not get what they bargained for. We agree with the district court's decision that there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law."

266 F.3d 669

The appeal court then concluded that the amount of defendant's gain, ie total sales price of the drugs was proper because:

"Here consumers bargained for FDA-approved drugs that were in compliance with the law. This they did not get."

266 F.3d 669

6. <u>Jury did not receive instructions on (a) How defendants violated CGMP or FDA regulations and (b) If defendant's CGMP or FDA violations were material if they did not affect the safety or efficacy of the drugs.</u>

In spite of defendants objections, both in Judge Grady's chambers and on record, Jury was given no instruction on how defendants violated CGMP or FDA regulations and if these violations were material, the appellate court justified its conclusions by stating:

> "The judge instructed the jury that the drug could have been adulterated in one of three ways. First, it could have been produced in a way that did not conform with the good manufacturing practices. Second, it could have decomposed to such a point that it no longer met applicable testing specifications. Third, the defendants could have added sodium hydroxide to it. The jury only had to find that any one of those three events occurred for the drug to be adulterated. The same is true for cound 6."
>
> 175 F.3d 579

In an attempt to tie Counts 3, 4, and 6 together, appellate court said:

> "However, since the jury found in count 4 that the defendants added sodium hydroxide to the Lactulose, then it implicitly found that the drug had been adulterated with respect to counts 3 and 6 as well."
>
> 175 F.3d 579

The above argument contradicts appellate courts argument on page 10&11 where the court stated that:

> "However, there was a gap between 1984 and 1990 where under the plain statutory language the failure to establish or maintain records under § 355(k) was not subject to criminal penalties. This time gap is of import to this case; the

> defendants' conduct charged under § 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct. As noted, the defendants argue that under the plain language of the statute they cannot be penalized for failing to establish and maintain records."
>
> 266 F.3d 665

and

> "[4] While the plain language of the FDCA clearly prohibited the failure to establish or maintain records, criminal penalties were not clearly imposed."
>
> 266 F.3d 668

Now Appellant's, Defendants argue that the government and the appellate court can not have it both ways as failure to maintain records is not the issue here because batch records were created and maintained. The only issue is if the omission or error (or falsification as to addition of sodium hydroxide the government may argue) in the batch records was material, is an issue for the jury. Jury was given no instructions on materiality as therefore government's arguments have no merits as a matter of law in light of *Neder v. United States* 527 U.S. 1(1999).

UNITED STATES of America, Plaintiff–Appellant,

v.

Baldev Raj BHUTANI, Neelam Bhutani, and ALRA Laboratories, Inc., Defendant–Appellee.

No. 98–1154.

United States Court of Appeals, Seventh Circuit.

Argued Nov. 13, 1998.

Decided April 28, 1999.

After they were convicted by jury of offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products, defendants moved for new trial. The United States District Court for the Northern District of Illinois, John F. Grady, J., 1997 WL 811689, granted motion. Government appealed. The Court of Appeals, Bauer, Circuit Judge, held that: (1) government did not violate its *Brady* obligation to disclose evidence when it failed to disclose new stability data for drug at issue in trial, and (2) defendants were not entitled to new trial on grounds of newly discovered evidence, based on new stability data.

Reversed and remanded.

1. Criminal Law ⇐1156(1)

Appellate review of a district court's granting of a new trial in a criminal case is deferential.

2. Criminal Law ⇐1139

Court of Appeals applies de novo review when its review of the granting of a new trial, based on a *Brady* violation arising from government's failure to disclose evidence, revolves around a pure issue of law.

3. Criminal Law ⇐700(2.1)

Government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant and is material to either the issue of guilt or punishment.

4. Criminal Law ⇐700(2.1)

For purposes of government's *Brady* obligation to disclose material, exculpatory evidence, favorable evidence will be considered "material" if its suppression undermines confidence in the outcome of the trial.

See publication Words and Phrases for other judicial constructions and definitions.

5. Criminal Law ⇐700(2.1)

To establish that government failed to disclose material, exculpatory evidence in violation of *Brady*, defendant does not have to show that it is more likely than not that the verdict would have been different if the evidence in question had been disclosed, but only that there is a reasonable probability that the outcome would have been different.

6. Constitutional Law ⇐268(5)

Any nondisclosure of material exculpatory evidence by the government results in a violation of the defendant's due process rights. U.S.C.A. Const.Amend. 5.

7. Criminal Law ⇐700(2.1, 6)

Even though the government has an affirmative duty to disclose exculpatory evidence in its possession, it is not obligated to disclose every possible shred of evidence that could conceivably benefit the defendant, nor does it have an obligation to turn over evidence of which it has no knowledge.

8. Criminal Law ⇐700(2.1)

Government cannot be found to have suppressed evidence if the same information was available to the defendant through the use of reasonable diligence.

9. Criminal Law ⇐700(7)

While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of *Brady* material will be imputed to the prosecution.

10. Criminal Law ⇐700(6)

Government did not violate its *Brady* obligation to disclose material, exculpatory evidence during trial for offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products when government failed to disclose new stability data for drug manufactured and distributed by defendants on which "bible" of pharmaceutical industry relied to publish, posttrial, recommendation to change drug's effective range; possession by Food and Drug Administration (FDA) of stability data from other pharmaceutical companies did not establish knowledge that change would be proposed. U.S.C.A. Const.Amend. 5.

11. Criminal Law ⇐700(2.1)

To be subject to government's disclosure obligations, *Brady* material must be (1) in the possession of the prosecution, (2) material, and (3) exculpatory.

12. Criminal Law ⇐700(2.1)

Government cannot be held responsible under *Brady* for failing to disclose merely speculative evidence.

13. Criminal Law ⇐938(1)

Under four-part test to determine whether defendant's motion for new trial based on newly discovered evidence should be granted, defendant must show that evidence at issue (1) came to his knowledge only after trial, (2) could not have been discovered sooner through use of due diligence, (3) is material and not merely cumulative or impeaching, and (4) would probably lead to acquittal in the event of new trial.

14. Criminal Law ⇐945(2)

Defendants charged with offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products were not entitled to new trial on grounds of newly discovered evidence, based on post-trial recommendation by industry "bible" to change effective range for one of drugs at issue, despite claim that change destroyed prosecution's theory that defendants adulterated drugs for profit purposes by eradicating need for defendants to spike certain drug lots to show that they remained within effective range, inasmuch as government's theory was not that drugs were or would soon be unfit for use, but that they were adulterated to conceal their age and permit their repackaging with extended expiration dates, and therefore change in effective range was of no consequence.

15. Criminal Law ⇐940

Even if defendants charged with offenses related to manufacture and distribution of mislabeled and/or adulterated generic pharmaceutical products were entitled to new trial on charges related to specific drug, based on newly discovered evidence, they were not entitled to new trial on charges pertaining to different drug, given that convictions on those charges were based on entirely different

set of facts and conduct, to which new evidence had absolutely no relation.

Susan E. Cox, Office of the United States Attorney, Criminal Division, Chicago, IL, Robert M. Loeb (argued), Department of Justice, Civil Division, Appellate Section, Washington, DC, for Plaintiff–Appellant.

Patrick A. Tuite (argued), Arnstein & Lehr, Steven M. Kowal, Burditt & Radzius, Chicago, IL, for Baldev R. Bhutani.

Steven M. Kowal, Burditt & Radzius, Chicago, IL, for Neelam Bhutani.

Patrick A. Tuite, Arnstein & Lehr, Chicago, IL, for ALRA Laboratories, Inc.

Daniel G. Jarcho, McKenna & Cuneo, Washington, DC, for Amicus Curiae National Pharmaceutical Alliance.

Before BAUER, RIPPLE, and EVANS, Circuit Judges.

BAUER, Circuit Judge.

On February 12, 1996, after a ten week trial, a jury found the three defendants, Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc., guilty of a number of charges related to their manufacturing and distribution of mislabeled and/or adulterated generic pharmaceutical products. After various post-trial motions were denied, the defendants filed a motion for a new trial based on newly discovered evidence and/or the government's violation of *Brady v. Maryland*, 373 U.S. 83, 83 S.Ct. 1194, 10 L.Ed.2d 215 (1963). The district court granted the defendants' motion for a new trial on all counts of conviction based on the government's violation of *Brady*. The government now appeals that ruling. For the reasons set forth below, we reverse.

I. BACKGROUND

Baldev and Neelam Bhutani are the husband and wife team that owns ALRA Laboratories, Inc., a pharmaceutical company that produces generic prescription drugs. The trial primarily focused on the manufacturing and distribution process of two drugs produced by ALRA—Lactulose and K+10. Lactulose is a drug used to combat advanced liver disease, and K+10 is a potassium supplement.

On January 26, 1994, a federal grand jury filed a superseding indictment charging all three defendants with violations of 21 U.S.C. §§ 331(a), 331(e), 331(k), and 333(a)(2) and Baldev Raj Bhutani and ALRA with violations of 18 U.S.C. §§ 2, 371, 1001, and 1341. The indictment charged all three defendants with (1) adulterating and mislabeling their Lactulose products; (2) keeping improper records with respect to the Lactulose; (3) failing to meet the good manufacturing practice standards; and (4) introducing the adulterated Lactulose into interstate commerce—all with the intent to defraud and mislead. Additionally, all three defendants were charged with adulterating and failing to keep proper records with respect to their K+10 drug. Lastly, Baldev Raj Bhutani and ALRA were charged with providing false statements to various divisions of the Food and Drug Administration ("FDA") and obtaining money through fraudulent schemes. While the trial delved into all of the charges against the defendants, this appeal relates only to a claim of the discovery of new, and the suppression of, evidence regarding the stability of Lactulose and the effect, if any, this had on the rest of the trial.

Lactulose is a drug that comes in a syrup form, much like the consistency of honey, that is used to treat the liver disease portal systemic encephalopathy. When an individual has this condition, the liver is unable to remove excess ammonia before it enters the bloodstream. Lactulose's function is to remove the ammonia from the colon and large intestine before it can enter the bloodstream. Lactulose is a disaccharide, meaning that it is a combination of two sugars. All drugs, including Lactulose, begin a degradation process af-

ter they are manufactured, which is why they are given expiration dates. As Lactulose ages, it breaks down into its component parts. Should it eventually decompose fully, a process that may take several years, then it would no longer be Lactulose, as the two sugars will have separated, rendering the drug ineffective. Only when the two sugars are combined may they act to remove ammonia from the colon and large intestine; neither sugar on its own can remove the ammonia. Without Lactulose, a person with portal systemic encephalopathy could slip into a coma caused by excess ammonia in the bloodstream.

One way of testing the stability of Lactulose is to measure its pH level. The pH scale measures the acidity or baseness of a chemical on a scale of 0 to 14. A chemical with a pH below 7 is an acid, while one with a pH above 7 is a base. At the time of the trial, the accepted pH range in which Lactulose was considered most effective, as set forth by the U.S. Pharmacopeia ("U.S.P."), also known as the "bible" of the pharmaceutical industry, was 3.0 to 7.0. The U.S.P. based this determination on stability data provided by various drug manufacturers to the FDA. As Lactulose ages and begins to degrade, it becomes more acidic, i.e. its pH drops. Thus, the older Lactulose gets, the lower its pH reading will become. If the pH level becomes too low, the drug will no longer be effective to fight the liver disease.

The main focus of that portion of the trial concerning ALRA's production of Lactulose centered around two separate lots of the drug: lots 52–230 and 52–231. At trial, the government claimed, and the jury found, that employees at ALRA, at the direction of Baldev Raj Bhutani, adulterated these lots of Lactulose by "spiking" them with the foreign substance sodium hydroxide in order to conceal their age. Sodium hydroxide is a base, and, when combined with a more acidic substance, will raise its pH level. The government introduced evidence that ALRA employees opened individual bottles of Lactulose from lots 52–230 and 52–231, spiked them with sodium hydroxide, re-sealed the bottles, and repackaged them for distribution with an erroneous expiration date.

Lots 52–230 and 52–231 were manufactured in June of 1986. However, ALRA did not obtain approval from the FDA until July of 1988 to distribute the drug. When ALRA finally received approval to market its Lactulose, it aimed to distribute these two lots of Lactulose by September of 1988. The government presented evidence at trial that lot 52–231 had a pH level of 4.6 in February of 1988 and a pH level of 6.6 in August of 1988. This change represents a 100–fold increase in pH (a chemical with a pH of 4.6 is 100 times more acidic than a chemical with a pH of 6.6). In addition, the government showed that lot 52–230's pH level increased from 4.7 to 5.1 over the same period of time. It was agreed at trial by both government and defense expert witnesses that there is no naturally occurring process which will increase the pH level of Lactulose over time.

Based on the evidence presented at trial, which consisted of expert testimony, testimony from employees of ALRA, and various data findings, on February 12, 1996, the jury found ALRA and Baldev Raj Bhutani guilty with respect to counts 3, 4, and 6 of the superseding indictment—charges relating to adulterating Lactulose, keeping inaccurate records, and sending the adulterated drug into interstate commerce. In total, the jury found ALRA guilty on 8 of 13 counts, Baldev Raj Bhutani on 7 of 13 counts, and Neelam Bhutani on 4 of 10 counts.

On July 5, 1996, after filing various motions for post-trial relief, the defendants filed a motion for a new trial based on newly discovered evidence and/or a *Brady* violation. They claimed that the government, at the time of the trial, had in its possession stability data from numerous drug manufacturing companies that showed that the effective range for Lactu-

lose was not in fact 3.0 to 7.0, and that Lactulose was still perfectly effective with a pH level as low as 2.5. Furthermore, they asserted that the U.S.P. released a proposal in May of 1996 to change the effective pH range for Lactulose from 3.0 to 7.0 to 2.5 to 6.5. The defendants argued that, under the standards set forth in *Brady*, the government was obligated to turn this information over to them. They further asserted that this new data completely undermines the government's theory of the case that the defendants were willing to put their own personal profits ahead of the safety of the public by putting adulterated drugs on the market. Additionally, they claimed that the government's theory had a prejudicial "spillover" effect in the jury's findings of guilty on all of the counts, even those counts unrelated to the production of Lactulose. Thus, they contend that all of the defendants are deserving of a new trial on all of their convictions.

The district court agreed with the defendants. The court stated that the government's prevailing theme throughout the case was the defendants' blatant disregard for public safety by shipping adulterated drugs into the marketplace just so they would not lose any profits by discarding the old, decomposed Lactulose lots. The court went on to say that since this new stability data showed that Lactulose was still effective at a lower pH level than the government represented at trial, the data tends to show that the defendants would have less of a reason to be nervous about a pH level of 4.6, and, therefore, had no need to spike the product to raise its pH level. Thus, the court determined that the government's suppression of this new stability data "seriously undermines the court's confidence in the verdict of the jury on Counts 3, 4 and 6." *United States v. Bhutani*, 1997 WL 811689 at *14 (N.D.Ill. 1997). In addition, the court found that all of the counts of conviction were so entwined in the government's profit motive theory that it ordered a new trial for all defendants on all of their convictions, even those unrelated to the Lactulose charges. The government now appeals that ruling.

II. DISCUSSION

[1, 2] Appellate review of a district court's granting of a new trial in a criminal case is deferential. *United States v. Boyd*, 55 F.3d 239, 242 (7th Cir.1995). However, when the review of a granting of a new trial based on a *Brady* violation revolves around a pure issue of law, our review is *de novo*. *United States v. Maloney*, 71 F.3d 645, 652–53 (7th Cir.1995), *cert. denied*, 519 U.S. 927, 117 S.Ct. 295, 136 L.Ed.2d 214 (1996).

A. *Brady* Violation

Federal Rule 33 of Criminal Procedure allows a court to grant a defendant's motion for a new trial if it is required in the interest of justice. A motion for a new trial based on newly discovered evidence must be made within two years after final judgment. The district court granted the defendants' motion for a new trial because it found that the government did not fulfill its duties under *Brady* by not disclosing the stability data that was under the control of the FDA. We do not agree that the government committed a *Brady* violation.

[3–6] Under *Brady* and its progeny, the government has an affirmative duty to disclose any evidence in its possession that is favorable to the defendant and is material to either the issue of guilt or punishment. *United States v. Gonzalez*, 93 F.3d 311, 315 (7th Cir.1996). Favorable evidence will be considered material if "its suppression undermines confidence in the outcome of the trial." *Id.* at 316 (quoting *United States v. Bagley*, 473 U.S. 667, 678, 105 S.Ct. 3375, 87 L.Ed.2d 481 (1985)). The defendant does not have to show that it is more likely than not that the verdict would have been different if the evidence in question had been disclosed, but only that there is a "reasonable probability" that the outcome would have been different. *Gonzalez*, 93 F.3d at 316 (quoting

Kyles v. Whitley, 514 U.S. 419, 434, 115 S.Ct. 1555, 131 L.Ed.2d 490 (1995)). Any nondisclosure of material exculpatory evidence by the government results in a violation of the defendant's due process rights.

[7, 8] Even though the government has an affirmative duty to disclose exculpatory evidence in its possession, it is not obligated to disclose "every possible shred of evidence that could conceivably benefit the defendant." *United States v. Hamilton*, 107 F.3d 499, 509 (7th Cir.1997), *cert. denied*, 521 U.S. 1127, 117 S.Ct. 2528, 138 L.Ed.2d 1028 (1997). Nor does it have an obligation to turn over evidence of which it has no knowledge. *Id.* Moreover, the government cannot be found to have suppressed evidence if the same information was available to the defendant through the use of reasonable diligence. *United States v. Morris*, 80 F.3d 1151, 1170 (7th Cir. 1996), *cert. denied*, 519 U.S. 868, 117 S.Ct. 181, 136 L.Ed.2d 120 (1996).

[9] While the government does not have the duty to disclose information of which it is unaware, if a government agency is charged with the administration of a statute and has consulted with the prosecution in the case, the agency will be considered part of the prosecution, and its knowledge of *Brady* material will be imputed to the prosecution. *See United States v. Wood*, 57 F.3d 733, 737 (9th Cir. 1995); *United States v. Anderson*, 36 F.Supp.2d 1264, 1267 (D.Kan.1998). "The government cannot with its right hand say it has nothing while its left hand holds what is of value." *Wood*, 57 F.3d at 737.

The material that the defendants claim was suppressed by the government is data that was in the possession of the FDA at the time of trial which said that Lactulose was perfectly stable and effective with a pH level as low as 2.5. Based on this evidence, the defendants claim that as early as late 1995, the U.S.P. planned to recommend a proposed change in the effective range of Lactulose syrup from 3.0 to 7.0 to 2.5 to 6.5. Therefore, the defendants contend that this information which was in the possession of the FDA was helpful to their case because, had they known of the proposed change, they would have informed the jury of the same and argued that the Lactulose was still effective when the alleged spiking incident occurred. The defendants claim that this evidence undermines the government's theory of the case since the defendants would have had no reason to spike the lots in question. As it turns out, the U.S.P. eventually published its proposal to change the effective pH range of Lactulose in May of 1996, three months after the jury's verdict.

[10–12] While we agree with the defendants that information held by the FDA can, in this case, be imputed to the prosecution, we do not agree that the evidence in question is *Brady* material. *Brady* material must be (1) in the possession of the prosecution; (2) material; and (3) exculpatory. *United States v. Hartbarger*, 148 F.3d 777, 786 (7th Cir.1998), *cert. denied*, — U.S. ——, 119 S.Ct. 1117, 143 L.Ed.2d 112 (1999). We disagree that the evidence in question was in the possession of the prosecution. The real evidence that the defendants rely on in their motion is the eventual publication of the U.S.P.'s proposal to lower the effective range of Lactulose. This was not published until well after the trial had ended. Simply because the FDA had stability data from other pharmaceutical companies does not mean that they had any knowledge that the U.S.P. was going to recommend the proposed change in Lactulose's effective pH range. The government cannot be held responsible for failing to disclose merely speculative evidence. *United States v. Agurs*, 427 U.S. 97, 109, 96 S.Ct. 2392, 49 L.Ed.2d 342 (1976), n. 16. Since we find that the evidence in question was not within the possession of the government, we need not decide whether it was exculpatory or material. Therefore, we disagree with the district court that the defendants should have been granted a

new trial based on the government's alleged *Brady* violation.

B. Newly Discovered Evidence

[13, 14] Even though the evidence in question was not within the possession of the prosecution, the defendants may, nevertheless, be entitled to a new trial based on newly discovered evidence, an alternative theory raised in their motion for a new trial. The standard for determining whether a defendant is entitled to a new trial based on newly discovered evidence is different from that of determining whether one is entitled to a new trial because of a *Brady* violation. We have evolved a four part test to determine whether a defendant's motion for a new trial based on newly discovered evidence should be granted. The defendant must show that the evidence at issue (1) came to his knowledge only after the trial; (2) could not have been discovered sooner through the use of due diligence; (3) is material and not merely cumulative or impeaching; and (4) would probably lead to an acquittal in the event of a new trial. *Gonzalez*, 93 F.3d at 315.

The defendants argue that the U.S.P.'s recommendation to lower the effective range of Lactulose would have been helpful to their case because it would have destroyed the prosecution's profit-motive theory. They argue that since Lactulose does not lose any of its laxative effect and is still effective with a pH as low as 2.5, then there was no reason to spike the lots in question. The district court agreed with them. We find that both the defendants and the district court mischaracterized the prosecution's argument.

The district court's decision relies heavily on the idea that the government portrayed the defendants as profit-hungry monsters who were willing to put the public's safety at risk in order to make a buck by putting ineffective drugs on the market. The court said that the government argued that the defendants spiked their Lactulose lots because they wanted to mask the fact that the product would soon be unfit for use. *Bhutani*, 1997 WL 811689 at *12 (N.D.Ill.1997). Thus, the district court concluded that the new evidence undermines the government's profit-motive theory and the jury could very well have reached a different conclusion had it known of the new effective range.

We agree that the government's theory was that the defendants were driven by the desire to make a profit, but, after reviewing the trial transcript, we do not agree that the government's argument was premised on the fact that ALRA spiked the Lactulose lots because they would soon be unfit for use. In fact, the government did not argue that the Lactulose was unfit, or close to unfit. What the government did argue was that the defendants spiked the Lactulose lots because the lots were old and they wanted to conceal their age to make them look like newer lots of Lactulose produced by ALRA. The reason for this is that the FDA has determined that Lactulose should be marketed with an expiration date that is 18 months after its manufacture. Here, the lots in question were all manufactured in 1986 and not distributed until 1988. In order for the defendants to sell their product, it had to conform to FDA standards. Thus the defendants had to conceal the *age* of the product. They did this by raising the pH levels and marking the lots with expiration dates of September 1989. The government did not argue that the pH level in the lots in question ever dropped below 3.0. In fact, when the government's expert witness, Dr. Hicks, was questioned by defense counsel, he stated that the pH levels were never outside of the effective range. Thus, it was the defense, and not the government, that put the effective range at issue in the first place. Neither Dr. Hicks, nor any other government witness, ever testified that the Lactulose in question was ineffective. The adulterated lots had the potential of becoming unsafe while in the marketplace with an inaccurate expiration date, but were not necessarily unsafe at

the time of distribution. The government argued that the defendants put the public's safety at risk by supplying adulterated products, not necessarily ineffective ones.

Throughout the trial, the defendants contended that the spiking incident never occurred. However, based on all of the evidence, the jury simply believed the prosecution's case over the defendants'. The prosecution presented expert witnesses who testified that there is no naturally occurring process which can reverse the trend of Lactulose's degradation. In addition, the government called former employees who participated in the spiking incident to describe the process that was used in adding the sodium hydroxide to the Lactulose syrup. Those employees described, in detail, the "assembly line" type procedure that was used in opening the Lactulose bottles, injecting them with sodium hydroxide with a turkey baster type instrument and later a syringe, re-sealing the bottles, and re-packaging them with falsified expiration dates. The government also presented employee time cards with extensive overtime recorded on the days the spiking incident occurred. Lastly, these employees testified that Baldev Raj Bhutani oversaw and authorized the entire operation. The defense had ample opportunity to cross examine these witnesses, and indeed they did. The fact that the U.S.P. subsequently proposed a lower effective pH range for Lactulose is of no consequence to the case since the government never argued that the Lactulose's pH was outside of the effective range, or even close to being outside the range.

The trial judge properly instructed the jury on what it must unanimously find in order to convict the defendants on counts 3, 4, and 6. Count 4 charged that the defendants, with the intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the Lactulose lots in question. In order to find the defendants guilty of this count, the jury had to unanimously find that the defendants injected the lots with sodium hydroxide. The jury unanimously found this with respect to Baldev Raj Bhutani and ALRA, but not Neelam Bhutani. For count 3, the jury had to find that the lots of Lactulose were adulterated. The judge instructed the jury that the drug could have been adulterated in one of three ways. First, it could have been produced in a way that did not conform with the good manufacturing practices. Second, it could have decomposed to such a point that it no longer met applicable testing specifications. Third, the defendants could have added sodium hydroxide to it. The jury only had to find that any one of those three events occurred for the drug to be adulterated. The same is true for count 6.

Arguably, the new proposal by the U.S.P. could have shown that the Lactulose still met specifications even though it had degraded some. However, since the jury found in count 4 that the defendants added sodium hydroxide to the Lactulose, then it implicitly found that the drug had been adulterated with respect to counts 3 and 6 as well. Its finding in count 4 acts as an independent basis of a finding of adulteration for counts 3 and 6. Therefore, while the new data could show that the Lactulose had not degraded to the point of making it unsafe, the jury nonetheless found that the drug was adulterated by the addition of sodium hydroxide. Thus, the defendants are not entitled to a new trial for counts 3, 4, and 6 based on newly discovered evidence.

C. The Spillover Effect

[15] Lastly, the district court ruled that all of the defendants were entitled to a new trial on all of their convictions, even those unrelated to Lactulose, because all of the charges were so entwined with the government's profit-motive theory that it influenced the jury's decision on the other counts. Since we have determined that the defendants are not entitled to a new trial for counts 3, 4, and 6 because of the new evidence, it necessarily follows that

there could be no spillover effect on the other counts. Even if we were to find that the defendants were entitled to a new trial for the Lactulose charges, the other convictions were based on an entirely different set of facts and conduct for a different drug altogether. These convictions were based on the manufacturing of K+10 and how a foreign substance was accidentally introduced into the mixing process, yet the drug entered the marketplace regardless. Even if the new evidence would have led to a different outcome in counts 3, 4, and 6, the new evidence has absolutely no relation to the conduct for which the defendants were found guilty in the manufacturing and record keeping of K+10. These violations contain completely different elements and are not related to the U.S.P.'s new proposal whatsoever. The jury found beyond a reasonable doubt that the defendants were guilty of these counts regardless of the Lactulose charges as evidenced by the fact that it did not find that Neelam Bhutani was guilty of counts 3, 4, and 6, but that she was guilty for her role with respect to the K+10 offenses. Therefore, the defendants are not entitled to a new trial on these additional counts.

III. CONCLUSION

For the reasons set forth above, we REVERSE the district court's ruling that the defendants are entitled to a new trial on all of their convictions based on a *Brady* violation or newly discovered evidence and REMAND to the district court with orders to reinstate the verdicts of conviction and to sentence the defendants to appropriate terms as prescribed by the Sentencing Guidelines.

UNITED STATES of America,
Plaintiff Appellee,

v.

Baldev R. BHUTANI and ALRA Laboratories, Incorporated,
Defendants–Appellants.

Nos. 00–1523, 00–2679.

United States Court of Appeals,
Seventh Circuit.

Argued April 5, 2001.

Decided Sept. 12, 2001.

Rehearing and Rehearing En Banc Denied Nov. 14, 2001.

Following overturn on appeal, 175 F.3d 572, of grant of new trial to defendants who had been convicted of offenses related to manufacture and distribution of mislabeled and/or adulterated pharmaceutical products, the United States District Court for the Northern District of Illinois, John F. Grady, J., on remand for sentencing, denied new motion for new trial. Defendants appealed. The Court of Appeals, Bauer, Circuit Judge, held that: (1) gov-

ernment's position on appeal did not contradict its theory at trial; (2) defendants were subject to criminal penalties despite error which left penalties out of statute during period of offenses; (3) sentencing under guideline for fraud and deceit was proper; (4) sentencing under guideline which went into effect after defendants' offenses was proper; and (5) defendant's gain was appropriate measure of loss attributed to fraud.

Affirmed.

1. Criminal Law ⇐1192

Government's position on appeal did not contradict its trial theory, and so new trial was not warranted on remand on ground that government's appellate position was newly discovered evidence; government, in prosecution for mislabeling and adulteration of pharmaceutical products, consistently maintained that defendants added sodium hydroxide to liver disease drug for purpose of disguising fact that drug was degrading due to being past its expiration date.

2. Statutes ⇐241(1)

Generally, courts strictly construe criminal statutes against government and in defendant's favor, so as to ensure that people are fairly warned about what sort of conduct may expose them to criminal penalties and what sort of penalty may be imposed.

3. Statutes ⇐235

In strictly construing a statute, courts ought not deprive it of obvious meaning intended by Congress, nor abandon common sense.

4. Drugs and Narcotics ⇐43.1

Defendants' failure to establish or maintain accurate drug manufacturing batch production records in accordance with requirements of Food, Drug, and Cosmetic Act (FDCA) was subject to criminal penalties despite typographical error in amending of statute which apparently eliminated penalties while maintaining requirement for records, during time of defendants' actions; strict reading of FDCA as it was at time of offense put plain language at odds with statute's purpose and intent, and there was no indication in legislative history that in amending FDCA Congress intended to eliminate penalties. Federal Food, Drug, and Cosmetic Act, § 301(e), 21 U.S.C.A. § 331(e).

5. Criminal Law ⇐1139

District court's choice of which sentencing guideline to apply is a question of law, and Court of Appeals reviews this choice de novo. U.S.S.G. § 1B1.1 et seq., 18 U.S.C.A.

6. Criminal Law ⇐1158(1)

Court of Appeals reviews factual determinations for clear error.

7. Sentencing and Punishment ⇐653(7)

Defendant who was convicted of mislabeling and adulterating pharmaceuticals was properly sentenced under sentencing guideline that applied to fraud and deceit, rather than provision covering violations of drug product regulations; there was substantial evidence of fraud in the case. U.S.S.G. §§ 2F1.1, 2N2.1(a), 18 U.S.C.A.

8. Sentencing and Punishment ⇐664(4)

Judges must apply the Sentencing Guidelines in force when a defendant is sentenced. U.S.S.G. § 1B1.1 et seq., 18 U.S.C.A.

9. Sentencing and Punishment ⇐736

Defendant's gain from sale of mislabeled and adulterated drugs was appropriate measure of loss attributed to fraud, for purposes of calculating base offense level for offense involving fraud; consumers bargained for FDA-approved drugs that were

in compliance with the law but got drugs that had been mislabeled and adulterated. U.S.S.G. § 2F1.1, 18 U.S.C.A.

10. Sentencing and Punishment ⇐736

In calculating loss attributed to fraud for purpose of calculating base offense level, district court is not required to compute the loss with precision; court need only make a reasonable estimate of loss based on information available. U.S.S.G. § 2F1.1, 18 U.S.C.A.

11. Sentencing and Punishment ⇐736

In calculation of loss attributable to fraud, for purpose of calculating base offense level, amount of defendant's gain may provide reasonable estimate of loss if more precise way of measuring loss is unavailable, so long as it has been shown that victims of the fraud suffered loss. U.S.S.G. § 2F1.1, 18 U.S.C.A.

Lawrence G. McDade (argued), Department of Justice, Consumer Litigation, Robert M. Loeb, Department of Justice, Civil Division, Appellate Section, Washington, DC, Barry Rand Elden, Chief of Appeals, Office of the U.S. Attorney, Criminal Division, Chicago, IL, for plaintiff-appellee.

Christopher B. Mead, London & Mead, Douglas B. Farquhar, Hyman, Phelps & McNamara, Washington, DC, for defendants-appellants.

Before BAUER, RIPPLE, and EVANS, Circuit Judges.

BAUER, Circuit Judge.

A jury found defendants Baldev Raj Bhutani, Neelam Bhutani, and ALRA Laboratories, Inc. guilty of various violations of the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* The defendants moved for a new trial, which the district court granted, finding that the government violated *Brady v. Maryland*, 373 U.S. 83, 83 S.Ct. 1194, 10 L.Ed.2d 215 (1963). The government appealed, and in *United States v. Bhutani*, 175 F.3d 572 (7th Cir.1999) we reversed and remanded the case for sentencing. On remand, the defendants again moved for a new trial, which the district court denied. Assuming familiarity with our first opinion, we consider the appeal by the defendants (Neelam does not appeal) from that denial. For the following reasons, we affirm.

A.

[1] The defendants believe that the government's position in the first appeal contradicted its trial theory and that the government's appellate position is newly discovered evidence, and that if the jury had heard the government's appellate theory it would have decided the case differently. Specifically, they contend that at trial the government said that the defendants had added sodium hydroxide to decomposed Lactulose in hopes of concealing its medical ineffectiveness, but on appeal admitted that the Lactulose was medically effective by iterating that it was within the accepted pH range before the addition of sodium hydroxide. On remand, the district court agreed with the defendants that the government had changed its theory, but the district court refused to entertain the argument, believing that it was foreclosed from doing so since we had held otherwise in our first opinion in this case.

The government counters that its focus at trial was not that the Lactulose was outside of the acceptable pH range or medically ineffective, but rather the fact that the defendants added sodium hydroxide to the Lactulose lots because they wanted the 1986 lots to have a pH similar

to the 1988 lots so that they could bear the same expiration date and be sold. The government's position was that the defendants masked the fact that the Lactulose was degrading and past its expiration date in order to make money.

We agree with the government. A second read of the trial transcript reveals that the government's position at trial and on appeal has been consistent. The government did not show at trial that the Lactulose was outside the accepted pH range or medically ineffective; rather it admitted that the pH was at all times within range, but that it was dropping, which signaled degradation, and in order to mask any degradation the defendants raised the pH by adding sodium hydroxide so that the fact that it was being sold past its expiration date could not be detected. The medical efficacy of the Lactulose was only mentioned by the government to explain the significance of expiration dating to the jury. The government wanted to explain why expiration dates are imposed in order to counter the defense theory that the defendants did not intend to put an adulterated product on the market because Lactulose could be stable and medically effective beyond the artificially imposed expiration date assigned by the "paperwork bureaucracy" known as the FDA. The defense again mischaracterizes the thrust of the government's case and regurgitates its argument from the last appeal, the only difference being that in the first appeal they argued that the newly discovered evidence was the U.S.P. recommendation, *see* 175 F.3d at 578–79, and here they point to the government's switch in theories. This supposed difference does not affect our decision. There is no new evidence that would have altered the outcome of this case.

B.

The defendants submit that reversal is justified because the district court abused its discretion, *see United States v. Butler*, 71 F.3d 243, 250 (7th Cir.1995), by permitting the government to elicit impermissibly prejudicial testimony from Dr. John Senior, offered as an expert in gastroenterology and liver disease, *see* Trial Tr. at 1691 (December 28, 1995), about the medical consequences of taking ineffective Lactulose. The defendants claim that Dr. Senior testified that patients could die from ingesting ineffective Lactulose. Before Dr. Senior testified, the district court had admonished the government to avoid introducing this sort of testimony. The defendants believe that the government violated this admonition.

Contrary to the defendants' characterization of Dr. Senior's testimony, the transcript reveals that he did not testify in an impermissibly prejudicial manner. Dr. Senior explained that Lactulose works as a substitute liver for patients with liver disease, and that Lactulose would be ineffective if it had degraded into its component parts because the separate sugars would be absorbed into the small intestine before reaching the colon. He also testified that it would be impossible for a physician to know that Lactulose had degraded to the point of ineffectiveness, and therefore a physician might erroneously determine that the Lactulose was ineffective for a patient for some other reason.

The sole mention of the possibility of death from ingesting ineffective Lactulose was not presented by the government, but was elicited on cross-examination by the defense:

Q. [Mr. Branding, Attorney for ALRA] And [Lactulose] doesn't cure the underlying liver disease, does it?

A. Of course not.

Q. It's only—

A. It's only a compensation for a failed organ.

Q. It's used to treat the symptoms?

A. It's used to treat—it's not just symptoms. It's a whole syndrome that may kill. It's not just symptoms.

Encephalopathy due to liver failure may be fatal. It's not just symptoms.

Trial Tr. at 1710–11 (December 28, 1995). The testimony defendants complain about was never offered, and thus there was no abuse of discretion by the district court.

C.

The defendants argue that Count Four, which charged that the defendants "[o]n or about August 12, 1988 ... with intent to defraud and mislead, failed to establish and maintain accurate drug manufacturing batch production records for the generic drug product, Lactulose Syrup USP" in violation of 21 U.S.C. § 331(e), along with the correlating conspiracy charge in Count One, failed to state a crime for which they could be convicted.

In 1938, Congress enacted the FDCA pursuant to its authority to regulate interstate commerce in order to protect the public from dangerous food and drug products. In 1962, Congress amended the FDCA, adding § 355(j) to require drug manufacturers to establish or maintain records about the manufacture and testing of drugs. *See* The Drug Amendments of 1962, Pub. L. No. 87–781, § 103(a), 76 Stat. 780. Thereafter, the failure to establish or maintain records under § 331(j) was a prohibited act under § 331(e) and subject to the imposition of criminal penalties under § 333, such as imprisonment, fine, or both.

In 1984, Congress amended the FDCA and the federal patent laws to help make available more low cost drugs by creating an abbreviated procedure for FDA approval of generic drug applications. *See* Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98–417, § 101, 98 Stat. 1585; *see also National Ass'n of Pharm. Mfrs., Inc. v. Ayerst Labs.*, 850 F.2d 904, 907 (2d Cir.1988). Congress enacted this new abbreviated drug approval process under § 355(j) and redesignated the old § 355(j) concerning record keeping as § 355(k). However, Congress did *not* alter § 331(e). Thus, § 331(e) still instructed that the failure to establish or maintain records under § 355(j) was subject to criminal penalties, even though the new § 355(j) did not require record keeping. Whether intentional or not, the penalties for failing to establish or maintain records had been in effect eliminated.

In 1990, Congress passed a short, technical amendment, which stated: "Section 301(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 331(e)) is amended by striking out 'or (j)' and inserting in lieu thereof 'or (k).'" Vaccine & Immunization Amendments of 1990, Pub. L. No. 101–502, 104 Stat. 1285. Thus, by simply replacing "(j)" with "(k)," § 331(e) again clearly subjected violators to the same criminal penalties as they had been for more than two decades prior to 1984 for failing to establish or maintain records.

However, there was a gap between 1984 and 1990 where under the plain statutory language the failure to establish or maintain records under § 355(k) was not subject to criminal penalties. This time gap is of import to this case; the defendants' conduct charged under § 331(e) occurred in August of 1988, which raises the delicate question of whether their convictions for these violations may stand, given that the plain language of the statute did not penalize their conduct. As noted, the defendants argue that under the plain language

of the statute they cannot be penalized for failing to establish and maintain records. The government argues that the elimination of the penalty was a scrivener's snafu, and criticizes the defendants' hyper-technical and illogical reading of the statute. This question has all of the trappings of a law school hypothetical, but with real-world consequences, so although the defendants' brief fails to support this argument with case law discussion or even citation, we nonetheless address this important issue of criminal law and statutory construction.

[2, 3] Generally, courts strictly construe criminal statutes against the government and in the defendant's favor. *See Barrett v. United States*, 423 U.S. 212, 218, 96 S.Ct. 498, 46 L.Ed.2d 450 (1976); 3 NORMAN J. SINGER, SUTHERLAND STATUTORY CONSTRUCTION § 59.03 (5th ed. 1992). This is so to ensure that people are fairly warned about what sort of conduct may expose them to criminal penalties and what sort of penalty may be imposed. *See United States v. Bass*, 404 U.S. 336, 348, 92 S.Ct. 515, 30 L.Ed.2d 488 (1971); 3 SUTHERLAND STATUTORY CONSTRUCTION § 59.03. But, in strictly construing a statute, courts ought not deprive it of the obvious meaning intended by Congress, nor abandon common sense. *See United States v. Moore*, 423 U.S. 122, 145, 96 S.Ct. 335, 46 L.Ed.2d 333 (1975); 3 SUTHERLAND STATUTORY CONSTRUCTION § 59.06.

Some courts have upheld the imposition of criminal penalties despite the presence of a typographical error in the statute. *See United States v. Lacher*, 134 U.S. 624, 625–32, 10 S.Ct. 625, 33 L.Ed. 1080 (1890) (upholding conviction for embezzling a letter containing an article of value under 18 U.S.C. § 318 even though after revision of the statute the wording was altered because "the intention to impose a penalty on [the] commission [of the offense] cannot reasonably be denied; and, although the apparent grammatical construction might be otherwise, the true meaning, if clearly ascertained, ought to prevail"); *United States v. Graham*, 169 F.3d 787, 790–91 (3d Cir.1999) (upholding a defendant's sentence for illegally reentering the United States after finding that Congress intended that the actual term of imprisonment imposed determines whether a defendant is classified as an "aggravated felon" under 8 U.S.C. § 1101(a)(43) despite the fact that the statutory section was "obviously missing a crucial verb"); *United States v. Warren*, 149 F.3d 825, 827–28 (8th Cir. 1998) (affirming the defendant's sentence of 151 months for manufacturing 32,000 grams of methamphetamine under 21 U.S.C. § 841(b)(1) even though "[a]t the time of [the] offense, because of a typographical error, the same amount of a quantity of a mixture—100 grams—was listed as triggering both the five-year and the ten-year mandatory minimum sentences," because Congress intended drug trafficking penalties to be graduated according to drug quantity); *United States v. Rossetti Bros., Inc.*, 671 F.2d 718, 720 (2d Cir.1982) ("Plainly, Congress did not intend its recodification [of the Interstate Commerce Act] to reduce the reach of [its] penalty, but intended merely to transplant that section, renumbered, into the recodified portion.... Congressional drafters unfortunately overlooked [this], but, when construed in light of the intent of Congress and in light of common sense, that section clearly applies to the regulations here in question."); *United States v. Scrimgeour*, 636 F.2d 1019, 1021–24 (5th Cir. Unit B 1981) (reversing dismissal of indictment under 18 U.S.C. § 1623(d) for making false declarations before a grand jury because in finding Congress' intention in enacting the statute, the court believed Congress inadvertently used an "or" in the statute but meant to use "and"); *United*

States v. Moore, 613 F.2d 1029, 1039–45 (D.C.Cir.1979) (same); *United States v. Babcock*, 530 F.2d 1051, 1053–54 (D.C.Cir. 1976) (holding that, in light of "an inadvertent change" by Congress when reorganizing and renumbering the statute, 2 U.S.C. § 441(b) was not to be interpreted to mean that a misdemeanor violation under § 440 precluded being sentenced to imprisonment); *cf. Whitfield v. Scully*, 241 F.3d 264, 272 (2d Cir.2001) ("Although the statute refers to [28 U.S.C.] § 1915(a)(2) for the manner of payment, we have recognized that this reference is a typographical error (as it makes the statute unintelligible) and that the actual process for payment of costs is instead described in § 1915(b)(2)."); *Estate of Kunze v. C.I.R.*, 233 F.3d 948, 953 (7th Cir.2000) ("The erroneous cross reference in [26 U.S.C. § 7430(c)(4)(D)] to a misnumbered subparagraph in (4)(A) can hardly be construed to have changed the legislative intent ... or to have affected the substantive rights of the parties. The import of the subsection remains clear, in spite of the typo."); *In re Chateaugay Corp.*, 89 F.3d 942, 952 (2d Cir.1996) (agreeing with other courts that the improperly renumbered subsections in 11 U.S.C. § 507 were the result of typographical errors by Congress rather than substantive changes in the law).

However, some courts have held otherwise. *See United States v. Faygo Beverages, Inc.*, 733 F.2d 1168, 1170 (6th Cir. 1984) (recognizing that Congress unintentionally eliminated a penalty section in recodifying the Interstate Commerce Act, but holding that the defendant was not subject to criminal penalty for his conduct because "it would be unreasonable to require persons confronted with the plain language of a criminal statute to go beyond that statute in order to determine whether Congress really meant what it clearly said"); *United States v. RSR Corp.*, 664 F.2d 1249, 1253–55 (5th Cir.1982) (noting that Congress inadvertently changed a penalty section in recodifying the Interstate Commerce Act, but holding that the defendant was not subject to criminal penalty for his conduct, stating "although this is what Congress clearly meant to say, intended to say, and wanted to say, still Congress did not say it").

[4] While the plain language of the FDCA clearly prohibited the failure to establish or maintain records, criminal penalties were not clearly imposed. Nevertheless, we agree with the reasoning found in the former set of cases rather than the latter because strictly reading and applying the FDCA as it was at the time of the offense in question would put the plain language at odds with the statute's purpose and intent. There is no indication in the legislative history that in amending the FDCA Congress intended to eliminate the penalties. The Law Revision Counsel of the House of Representatives, who prepares and publishes the U.S. Code, even placed a footnote in the 1988 edition of the U.S. Code in § 331(e) after the proscription on failing to keep records under § 355(k), and noted that § 335(j) had been redesignated as § 355(k). Thus, it seems that the failure to cross-reference the sections was interpreted as a mere typo by the Law Revision Counsel. Also, we agree with the government that Congress would not have eliminated the penalties for failing to establish or maintain records in this part of the statute while retaining the penalties for failing to do so under other sections. Furthermore, the government points out that the 1984 amendments broadened the record keeping requirements in the redesignated § 355(k), and that Congress would not have intentionally broadened the requirements and at the same time have eliminated the penalties for not complying with the requirements.

Finally, the defendants do not argue that because of the typographical error they lacked notice; nor could they since they maintained records believing that they were required to (although they did so inadequately, as this case reveals) under the FDCA. Therefore, we hold that the failure to establish or maintain records under § 355(k) was subject to criminal penalties despite the typographical error in § 331(e) between 1984 and 1990.

D.

[5, 6] Baldev Bhutani also raises several challenges to his sentence imposed under U.S.S.G. § 2F1.1 (2000). "The district court's choice of which guideline to apply is a question of law, and we review this choice *de novo*," United States v. Andersen, 45 F.3d 217, 219 (7th Cir.1995); we review factual determinations for clear error, *see United States v. Vitek Supply Corp.*, 144 F.3d 476, 490 (7th Cir.1998).

[7] First, the defendant finds error in the district court's choice of guideline to apply, claiming that he ought to have been sentenced under § 2N2.1(a) rather than § 2F1.1. Section 2N2.1(a) covers violations of statutes and regulations dealing with, among other things, drug products, and assigns a base offense level of six to such violations; however, subsection (b)(1) instructs: "[i]f the offense involved fraud, apply § 2F1.1 (Fraud and Deceit)." Section 2F1.1 "also has a base offense level of six, but provides for substantial increases in offense level based on the amount of loss." *Andersen*, 45 F.3d at 219. Bhutani's argument turns on the notion that § 2N2.1(a) applies because his wrongs were "knowing, technical" violations of the FDCA, and not as serious as those of other companies that have been prosecuted. This argument is without merit as there is substantial evidence of fraud in this case. *See, e.g., id.* at 219–20.

[8] Second, he submits that § 2N2.1(b)(1) does not apply to his case since it was made effective on November 1, 1992, but "the offenses of conviction all occurred prior to November 1, 1992." This is of no matter since "judges must apply the Guidelines in force when a defendant is sentenced." *United States v. Perez*, 249 F.3d 583, 584 (7th Cir.2001) (per curiam). Bhutani was sentenced on February 15, 2000, and subsection (b)(1) was then in effect, thus it is applicable.

[9–11] Third, the defendant disputes how the district court measured loss. As noted, sec. 2F1.1 assigns a base offense level of six, which is increased based on the amount of loss attributed to the fraud. In calculating the loss, the district court is not required under the Sentencing Guidelines to "compute the loss with precision; the court need only make a reasonable estimate of the loss based on the information available." *United States v. Duncan*, 230 F.3d 980, 985 (7th Cir.2000); *see* U.S.S.G. § 2F1.1, cmt. 9. If it has been shown that the victims of the fraud suffered a loss and a more precise way of measuring the loss is unavailable, the amount of the defendant's gain may provide a reasonable estimate of the loss. *See Andersen*, 45 F.3d at 221.

Directing us to *United States v. Chatterji*, 46 F.3d 1336 (4th Cir.1995), the defendant maintains that his gain was not the appropriate measure because there was no actual loss to consumers as none of the drugs were shown to be medically ineffective and there was no evidence that anyone fell ill or died. He argues that the calculation should not be based on whether the consumers got what they bargained for, but rather ought to be based on whether the consumers got medically ineffective drugs.

In *Chatterji*, the defendant, sentenced under U.S.S.G. § 2F1.1, submitted two abbreviated new drug applications to the FDA, which were approved. *See id.* at 1338–40. The defendant had submitted false batch records in its application for one of the drugs, and for the other had changed the formula by adding more of an inactive ingredient after its application had been approved without seeking further FDA approval. The district court held that loss should be measured by the defendant's gain from the sale of the drugs because the defendant's fraud voided the FDA approval, thereby stripping the drugs of market value. *See id.* at 1340. The Fourth Circuit, over dissent, reversed, finding that the defendant's gain was not the appropriate measure of loss because consumers got medically effective drugs that were exactly what they purported to be. *See id.* at 1340–43.

Relying on *United States v. Marcus*, 82 F.3d 606 (4th Cir.1996), the government in our case argues that there was loss to consumers because consumers paid for FDA-approved drugs, but received drugs that were not manufactured according to the FDCA and FDA regulations; therefore, the government argues that the amount of the defendant's gain is an appropriate measure of loss.

In *Marcus*, the defendant, sentenced under § 2F1.1, had obtained FDA approval to manufacture a drug, but changed the formula by adding two additional inactive ingredients without obtaining additional FDA approval. *See id.* at 607–08. The district court found that the defendant's gain was the appropriate measure of loss because the drug did not meet FDA specifications, and therefore, had no value. *See id.* at 608. The court distinguished *Chatterji*, which the Fourth Circuit affirmed, reasoning that the formula modification in *Chatterji* "was merely an insignificant change that implicated only the shelf life of the drug," and not the safety or medical efficacy; however, the formula modification here had a bearing on the medical effectiveness, which would require additional testing to determine whether the drug was still safe and effective. *Id.* at 610.

In this case, the district court agreed with the government's position and reasoned:

> I find the analysis in the *Marcus* case from the Fourth Circuit to be persuasive. I understand that the defendants believe *Marcus* is distinguishable on the basis that the defendant there agreed that there was an issue as to whether the drug involved there was the bioequivalent of the patented drug.
>
> I don't regard that as a distinguishing feature of the case, because whether the defendants stipulate to it or not, and certainly they do not in this case, I find that there was an issue as to whether these drugs had been properly manufactured.
>
> I'm not saying that there was an issue as to whether they would be injurious to health or necessarily even an issue as to whether they would be effective for their pharmaceutical purpose. What I find, rather, is that there was an issue as to whether they had been manufactured in such a way that the consumers of those drugs were being sold something other than what they thought they were buying.
>
> I don't think that any consumer of any of those drugs would have bought those drugs had the consumer known what had happened to them.
>
> * * *
>
> And I think the essence of the loss here to the consumers was the same thing fact [sic] that the *Marcus* case was

> talking about, namely, the fact that they didn't get the FDA-approved manufactured drugs that they thought they were getting.
>
> And I emphasize that I don't think *Marcus* applies only in the situation where the drugs could be dangerous. . . .

Sentencing Hr'g Tr. at 23–24 (February15, 2000). The district court based the amount of loss on the defendant's gain, which it estimated at over $200,000, thereby assigning Bhutani a base offense level of fourteen. *See* U.S.S.G. § 2F1.1(b)(1)(I).

While we do not agree with the district court's reading of *Marcus* or his reliance on it, we wholly adopt the core of its rationale. Indeed, we find the district court's reasoning to be more sound than that in *Chatterji* and *Marcus*.[1] The medical effectiveness of the drug or its dangerousness after adulteration ought not be the core of the inquiry; rather, the district court was justified in determining that there was a loss because consumers did not get what they bargained for. We agree with the district court's decision that there was indeed loss to consumers because consumers bought drugs under the false belief that they were in full compliance with the law.

However, the defendant points out that in *Andersen* we held that the defendant's gain was not the appropriate measure of loss when there was "no clear evidence that customers or consumers suffered any loss." 45 F.3d at 221. We so held, in part, because the drugs in that case were sold in hand-labeled containers and the customers were aware that the drugs were not FDA approved. *See* 45 F.3d at 221. That is not so here; here consumers bargained for FDA-approved drugs that were in compliance with the law. This they did not get. We agree with the district court's determination of what constitutes loss in this sort of case, and that the defendant's gain is the appropriate measure of that loss.

E.

The bulk of the defendants' brief is tinged with hyberbole, lamenting that they ought not to have been prosecuted because what they may have done was not so bad compared to what others have done and that their industry is over regulated by the FDA. The judiciary is not the branch to hear these beefs; rather, they ought to be raised with Congress, who makes the law, and prosecutors, who have broad discretion in instituting criminal proceedings. Furthermore, many of the disputes are no more than an invitation to reweigh the evidence based on the defendants' attempt to retry this case on appeal. We are at ease with the jury's work in weighing evidence and assessing credibility and will not engage in second-guessing. The other arguments of the defendants are equally without merit and we shall not address them further.

AFFIRMED.

1. We decline the defendant's invitation to apply *United States v. Maurello*, 76 F.3d 1304 (3d Cir.1996) by analogy to this case. We also find our decision in *Vitek Supply* inapplicable because it dealt with whether loss to competitors and downstream consumers was to be included in the loss calculation. *See* 144 F.3d at 490–92.