

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

FRANK JULIANELLO, on Behalf of  
Himself and All Others Similarly Situated,

Plaintiff,

v.

K-V PHARMACEUTICAL COMPANY,  
GREGORY J. DIVIS, JR. and SCOTT  
GOEDEKE,

Defendants.

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) Civil Action No.

)  
) CLASS ACTION COMPLAINT FOR  
) VIOLATIONS OF THE FEDERAL  
) SECURITIES LAWS

) JURY TRIAL DEMANDED

Plaintiff, Frank Julianello, alleges the following based upon the investigation by plaintiff's counsel, which included, among other things, a review of the defendants' public documents, conference call transcripts and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, and press releases, wire and press releases published by and regarding K-V Pharmaceutical Company ("K-V" or the "Company"), securities analysts' reports and advisories about the Company, and information readily available on the Internet. Plaintiff believes that substantial additional evidentiary support exists for the allegations set forth herein and will be available after a reasonable opportunity for discovery.

### **INTRODUCTION AND OVERVIEW**

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of the publicly traded securities of K-V between February 14, 2011 and April 4, 2011 (the "Class Period"), who were damaged thereby (the "Class").

2. K-V is a specialty pharmaceutical company that develops, manufactures, acquires and markets branded and generic/non-branded prescription pharmaceutical products. It operates in three segments: branded products, specialty generics and specialty raw materials. K-V has conducted its branded pharmaceutical operations through its subsidiary, Ther-Rx Corporation ("Ther-Rx") and its generic, non-branded operations through its subsidiary, ETHEX Corporation ("ETHEX").

3. In 2009, K-V and its subsidiaries, Ther-Rx and ETHEX, entered into a consent decree for making and distributing adulterated and unapproved drugs. That decree prohibited K-V from making or shipping drugs until the Company received FDA approval. In 2010, ETHEX pleaded guilty to two felony counts of criminal fraud for failing to report to the FDA that it was making oversized tablets that could be harmful to patients. As a result of this misconduct, Marc Hermelin, the former K-V chairman, was banned from participating in federal health programs such as Medicare and Medicaid. Hermelin was also ordered to pay a \$1 million fine, forfeit \$900,000 and serve a 30-day jail sentence. Since Hermelin remained a significant K-V

shareholder and director, K-V faced the possibility that it too might be banned. In the meantime, K-V began running low on cash and started to lay off workers.

4. Desperate, defendants turned to a drug called Makena as a lifeline. Makena is a prescription hormone (progestin) medicine used in women who are pregnant and who have delivered a baby too early (preterm) in the past. Makena is used in these women to help lower the risk of having a preterm baby again.

5. In generic form, Makena is referred to as 17P. First approved by the Food and Drug Administration (“FDA”) in 1956, it was manufactured by Bristol-Myers Squibb until production was stopped for commercial reasons in 2000. After that, the only makers were compounding pharmacies – pharmacies that custom make drugs in small quantities – which charged \$10 to \$20 per injection, amounting to \$200 to \$400 for the drug’s 20-week course. Then, in 2003, demand for 17P soared after a landmark study confirmed its effectiveness in preventing premature births.

6. Since it was decades old, 17P had no patent protection. But a law called the Orphan Drug Act (“ODA”) provides seven years of exclusive sales rights to manufacturers who win FDA approval for drugs that affect fewer than 200,000 people. The ODA is meant to encourage pharmaceutical companies to develop drugs for diseases that have a small market.

7. Under the ODA, K-V asked the FDA to grant 17P, rebranded as “Makena,” orphan drug status. After obtaining that designation, K-V then conducted a clinical trial of Makena and was granted FDA approval to manufacture and sell it on February 4, 2011. This approval gave K-V the exclusive right to market Makena, but it was unclear whether compounding pharmacies would be permitted to continue making and selling 17P, the generic version of Makena. Having obtained market exclusivity, defendants increased the price of Makena **1490%**, to \$1500.<sup>1</sup> Instead of costing \$200-\$400 for a course of treatment, the new cost would be \$15,000 to \$30,000.

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<sup>1</sup> All emphasis added throughout unless otherwise noted.

8. On February 14, 2011, the first day of the Class Period, defendants informed investors that K-V, through a program called the Makena Care Connection, would expand access to Makena to pregnant women who otherwise would not have had been able to obtain the drug from compounding pharmacists. Specifically, defendants stated that the Company would ensure “access for every eligible patient.” But the “list price” K-V was indicating to physicians was now \$1,500. Contrary to defendants’ February 14th representations, the financial assistance offered by the Makena Care Program was woefully insufficient to ensure access to all eligible patients in light of this astronomical price increase. This was not disclosed to investors, however, until March 17, 2011, when two U.S. Senators, Amy Klobuchar and Sherrod Brown, issued a press release and letter to the Federal Trade Commission (“FTC”). Regarding K-V’s attempt to provide financial assistance to help purchase Makena, the senators stated, “the financial assistance is not sufficient and does not extend to certain groups of women,” and so that in reality, ***“KV Pharmaceutical’s actions will result in diminished access to appropriate health care for women and result in increased preterm births.”***

9. As a result of this disclosure that, contrary to defendants’ earlier representations, K-V’s actions would reduce access to Makena, the price of K-V’s A series stock dropped from \$9.64 to \$8.50 in a single trading session. This decrease in the price of K-V’s stock was a result of the removal of some, but not all, of the artificial inflation caused by defendants’ misleading statements.

10. Defendants also lied about the FDA’s regulation of K-V’s competitors, stating that the FDA had no choice but to prohibit compounding pharmacists from making and selling generic Makena in competition with K-V. Specifically, defendants stated that the FDA’s enforcement discretion “does not extend to compounding of copies or essentially copies of commercially available FDA-approved products” like Makena.

11. On March 30, the FDA issued its own statement though, making clear that defendants’ representations were false. That statement said in relevant part:

FDA understands that the manufacturer of Makena, KV Pharmaceuticals, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. *This is not correct.*

In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate [Makena].”

12. With the FDA refusing to take enforcement action against compounding facilities prescribing 17P based on K-V’s previously undisclosed intent to gouge patients, defendants now had no protection from Makena’s competition in the market place. As a result of this disclosure, the price of K-V’s A series stock dropped from \$7.11 to \$5.65 in a single trading session on extremely high trading volume, with more than 25 million shares changing hands that day.

13. April 1, 2011, K-V would announce it was reducing Makena’s list price by nearly 55% to \$690 per injection versus the previous list price of \$1500, threatening to cause further erosion of K-V’s revenues and earnings.

14. The final shoe fell on April 4, 2011, when *Bloomberg* published a story entitled “KV Pharma’s Reduced Makena Price Won’t Sway Some Physicians,” which cited detailed interviews with several physicians and revealed that even with the 55% Makena list price reduction, prescribing physicians would not prescribe Makena to their patients. K-V’s stock price was hammered and fell an additional 9.5% in a single trading session, closing down at \$5.39 on April 4, 2011 from its close of \$5.99 the prior evening.

15. This decrease in the price of K-V’s stock was a result of the artificial inflation caused by defendants’ misleading statements coming out of the price. As the market fully absorbed this news, the Company’s stock price suffered further erosion and it now trades below \$2 a share. Meanwhile, the artificial price inflation defendants’ false and misleading statements caused during the Class Period enabled K-V to sell \$200 million worth of senior secured notes during the Class Period, used in large part to pay the Company’s debts. Class members were damaged by paying those artificially inflated prices for K-V stock and this action seeks recovery for them.

### **JURISDICTION AND VENUE**

16. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. K-V’s headquarters are located in St. Louis, Missouri and false statements were made in this District and acts giving rise to the violations complained of occurred in this District.

### **THE PARTIES**

17. Plaintiff Frank Julianello purchased K-V securities during the Class Period as set forth in the attached Certification and was damaged thereby.

18. Defendant K-V is a specialty pharmaceutical company with its headquarters in St. Louis, Missouri. K-V’s common stock is traded under the symbols K-Va and K-Vb on the New York Stock Exchange, which is an efficient market.

19. Defendant Gregory J. Divis, Jr. (“Divis”), was, at all relevant times, Chief Executive Officer (“CEO”) and President of the Company.

20. Defendant Scott Goedeke (“Goedeke”), was, at all relevant times, the Senior Vice President of Ther-RX Marketing and Market Access.

### **SCIENTER**

21. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of K-V securities during the Class Period.

### **PRE-CLASS PERIOD EVENTS**

22. 17P, the generic form of Makena, was approved by the FDA in 1956 and manufactured by Bristol Myers Squibb until 2000, when it was discontinued for commercial

reasons. After that, it continued to be manufactured by compounding pharmacists and sold for around \$20 per injection.

23. In 2003, demand for 17P soared after a landmark study confirmed its effectiveness in preventing premature births.

24. Subsequently, K-V applied to the FDA and Makena was granted orphan drug status, after which K-V conducted a clinical trial of the drug.

25. On February 4, 2011, defendants issued a press release that stated in relevant part:

K-V Pharmaceutical Company (NYSE: KVa/KVb) (the “Company”), a specialty pharmaceutical company, announced today that it has been informed by Hologic, Inc. that the U.S. Food and Drug Administration (FDA) granted approval for Makena™ (hydroxyprogesterone caproate injection). Makena, commonly referred to as “17P,” is the first and only FDA-approved treatment indicated to reduce the risk of preterm birth in women with a singleton pregnancy who have a history of singleton spontaneous preterm birth.

**FALSE AND MISLEADING  
STATEMENTS DURING THE CLASS PERIOD**

26. On February 14, 2011, defendants held a conference call with investment analysts. On that call, defendant Goedeke touted the expansion of patient access to Makena, stating:

Prior to FDA approval of Makena, mothers who could benefit from therapy faced significant barriers to accessing treatment due to the absence of a commercially available FDA-approved product. Our Company has carefully studied how to best remove these barriers and built our go-to-market strategy to ensure that we are in position to help fulfill the promise of Makena by facilitating access to this crucially important medication for every eligible patient.

27. On the same call, defendant Divis similarly stated:

As noted earlier, prior to FDA approval of Makena, women who could benefit from therapy that may reduce the risk of pre-term birth face significant barriers to access due to the absence of a commercially available, FDA-approved product. Because of these barriers, many eligible moms have been on the sidelines. As we have outlined, our Company recognizes the importance of addressing these barriers and is committed to helping fulfill the promise of Makena by ensuring access for every eligible patient.

28. Defendant Goedeke also engaged with the following colloquy with analyst Tim Chiang from CTR Capital regarding FDA regulation of compounding pharmacists that could potentially compete with K-V:

Hi, thanks. Greg, could you talk a little bit more about what the strategy is to get the off-label compounding pharmacies off the market? Is that something you have to do, or is that something the FDA will help you in doing?

Goedeke:

Tim, we believe that the regulations and laws are very clear. I think it's fair to say that compounding pharmacies are not FDA-approved manufacturing facilities and that FDA regulations and state pharmacy laws generally prohibit the distribution of compounded products that are the same or essentially the same as FDA-approved products. We also believe that compounded pharmacies are aware of these laws and regulations, and our expectation is that they will adhere to them. I think it's also fair to say that, despite the availability of compounded product, there have been moms on the sidelines because of significant logistical and financial barriers to access that are typically associated with non-FDA-approved products. And I'll just close by saying that everything we have designed around Makena is to remove these barriers and to make sure that we fulfill our corporate commitment, which is to make Makena accessible to all eligible patients.

29. On February 17, 2011, K-V issued a letter to compounding pharmacists that financial analysts took note of as well. That letter stated as follows:

It is our understanding that your pharmacy compounds human prescription drugs, including hydroxyprogesterone caproate injection [Makena]. Now that Makena is commercially available as the first and only FDA-approved hydroxyprogesterone caproate injection manufactured at a cGMP-facility, compounded, unapproved formulations of hydroxyprogesterone caproate injection should no longer be made by compounding pharmacies. Indeed, as articulated by the FDA in numerous enforcement actions, FDA has stated that it views compounded drugs to be "new drugs" within the meaning of 21 U.S.C. § 321(p), and as such, they may not be introduced into interstate commerce without FDA approval. Although FDA will exercise its enforcement discretion with respect to certain pharmacy compounding practices, *this discretion does not extend to compounding of copies or essentially copies of commercially available FDA-approved products*. Therefore, although compounding of hydroxyprogesterone caproate injection may have, in the past, been subject to FDA enforcement discretion, continuing to compound this product after FDA-approval of Makena renders the compounded product subject to FDA enforcement for violating certain provision of the Federal Food, Drug and Cosmetic Act, as well as FDA guidance. [footnotes omitted]

30. On March 1, 2011, defendants issued a press release that stated in relevant part:

March 1, 2011, St. Louis, MO – K-V Pharmaceutical Company (NYSE: KVa/KVb) (the "Company") announced today that it intends to offer \$200 million of senior secured notes due 2015 (the "Notes") in a private placement, subject to market conditions.

The Notes will be offered only to accredited investors pursuant to Regulation D under the Securities Act of 1933, as amended (the "Securities Act"). The Notes have not been registered under the Securities Act or any state or other securities laws and may not be offered or sold in the United States absent registration or an applicable exemption from registration requirements of the Securities Act and applicable state securities laws.

The Company intends to use the net proceeds from the offering of the Notes to repay in full the Company's outstanding obligations under its credit agreement with U.S. Healthcare I, L.L.C. and U.S. Healthcare II, L.L.C. (including the payment of related premiums) and terminate the related future loan commitments, to establish an escrow reserve for one year of interest payments on the Notes and for general corporate purposes.

### **DEFENDANTS' STATEMENTS WERE FALSE AND MISLEADING**

31. Defendants' statements set forth above were materially false and misleading. Contrary to their statements, K-V's marketing of Makena would restrict, not increase, patient access to the drug. Also contrary to defendants' statements, the FDA was not required to prohibit compounding pharmacists from manufacturing and selling generic Makena in competition with K-V.

### **THE TRUTH BEGINS TO EMERGE**

32. On March 17, 2011, U.S. Senators Amy Klobuchar and Sherrod Brown issued a press release regarding a letter they had sent to the FTC. That release stated in relevant part:

U.S. Senators Amy Klobuchar (D-MN) and Sherrod Brown (D-OH) today sent Federal Trade Commission Chairman Jon Leibowitz a letter urging the agency to launch an investigation into potentially anti-competitive behavior after a drug treatment used for high-risk pregnancies dramatically increased in cost. The drug, commonly known as Makena, is a weekly injection of progesterone meant to prevent pre-term labor in pregnant women and has been safely administered by U.S. pharmacies in the past at a cost of between \$10 and \$20 per injection. After the Missouri-based drug company K-V Pharmaceutical was granted orphan status for its version of the drug, the cost reportedly rose to \$1,500 per injection – 150 times the original cost.

"This is a proven and affordable drug that has been around for over 50 years. It's critical that we make sure this company isn't taking advantage of its orphan-drug determination to monopolize the market and engage in price gouging at the expense of pregnant women," Klobuchar said. "At a time when rising prices for prescription drugs are stretching the budgets of middle-class families, we must be vigilant in stopping practices that would limit access to vital medicines."

"KV created an overnight monopoly for this lifesaving drug – and then proposed raising the price by 14,900 percent," Brown said. "Last week, I called on KV Pharmaceuticals to immediately reconsider their decision, but to this date the company continues to defend this astronomical price increase. Price-gouging is never acceptable, particularly not when it undermines public health and fleeces taxpayers. Families deserve an investigation."

Last week, Brown sent a letter to KV Pharmaceutical urging the company to reverse course on the price increase for Makena. Brown called on the company to maintain access to the critical drug to stem an increase in premature births.

The drug first came to the market over 50 years ago and it has recently been used to help prevent early births in women who have a history of spontaneous pre-term deliveries. The price increase not only threatens to restrict individual access to the drug, it also places a heavy burden on state Medicaid programs, which cover a majority of high-risk pregnancies in this country.

33. The senators' press release also attached their letter to the FTC that stated in relevant part:

I am writing to request that the Federal Trade Commission initiate a formal investigation into any potential anticompetitive conduct arising out of KV Pharmaceutical's actions regarding a dramatic 150-fold increase in price that the company has applied to a proven progesterone treatment.

17-hydroxyprogesterone caproate, sold by KV Pharmaceutical under the name Makena, is a weekly injection of a form of progesterone meant to prevent preterm labor in high-risk pregnant women. This drug, which first came to market over 50 years ago, has recently been used to help prevent early births to women who had a history of spontaneous preterm deliveries. Prior to KV Pharmaceutical's actions, this product was mixed by compound pharmacies and administered safely for \$10 to \$20 per injection. Due to the product being given orphan drug status, KV Pharmaceutical has potentially created an anticompetitive market and has indicated they will dramatically increase the cost per injection to \$1,500.

While I understand the Food and Drug Administration (FDA) is working to ensure that drugs marketed and sold in the United States are safe and effective, I am concerned that KV Pharmaceutical is taking advantage of FDA's approval of Makena and orphan drug determination to achieve rights as the sole source for this limited use of progesterone, leading to a monopolization of treatments to address preterm labors.

I appreciate KV Pharmaceutical's attempt to provide financial assistance to help purchase Makena. However, the financial assistance is not sufficient and does not extend to certain groups of women. In addition [sic] to significant costs to individuals, this price increase will place a heavy burden on state Medicaid programs, which cover a majority of high-risk pregnancies. I am extremely concerned that ***KV Pharmaceutical's actions will result in diminished access to appropriate health care for women and result in increased preterm births.***

Thank you for your attention to my request.

34. As a result of this disclosure, the price of K-V's A series stock dropped from \$9.64 to \$8.50 in a single trading session. This decrease in the price of K-V's stock was a result of some of the artificial inflation caused by defendants' misleading statements coming out of the

price. The price of K-V stock remained inflated, however, because the full truth had yet to become public.

35. On March 23, 2011, the March of Dimes published a letter to defendant Divis that stated in relevant part:  
Dear Mr. Divis:

Thank you for your letter of March 17th. I am pleased to learn that you are 'listening carefully to stakeholder concerns about list price, patient access, and cost to payers'. Thank you for considering additional steps to ensure that Makena is available to all eligible women, and for convening stakeholders from the March of Dimes, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the Society for Maternal Fetal Medicine next week.

In advance of that meeting, I want to go on the record that March of Dimes expects Ther-Rx to come to the table with substantive commitments including:

1. A significant reduction in the list price of Makena.
2. Adjustments to the patient assistance program to ensure adequate coverage of all patients, insured, uninsured and underinsured.
3. A method for reporting on a regular basis to stakeholders on the patient assistance program to ensure that it is meeting needs in a timely and adequate way.
4. A justification or rationale for your pricing based on your investment in the product, savings to the health care system, or other appropriate methodology, which you are prepared to make public.

Without these elements, I do not believe that Makena can succeed in the current marketplace environment, and as a result, at-risk women will be denied access to a safe and effective treatment to reduce preterm delivery. Therefore if you are unable to make a clear commitment to significantly address the above issues at the meeting, the March of Dimes will need to pursue alternative strategies for ensuring that this proven intervention to prevent preterm birth is made available to all medically eligible pregnant women, and we will step away from our longstanding and productive corporate relationship with Ther-RX. Thank you for your consideration of this critical matter.

36. On March 30, 2011, defendants issued a press release that stated in relevant part:

To remove financial barriers to access, Ther-Rx established and has activated a patient financial assistance program (PAP) that not only reduces the total out-of-pocket costs for qualified patients, but eliminates out-of-pocket costs entirely for patients whose financial need is greatest. The level of assistance already exceeds many federal program guidelines for healthcare subsidies. Based on the feedback the company has received, we are currently exploring additional ways to help provide affordable access for all patients who are prescribed Makena. This includes the expansion of the existing patient assistance program.

37. On the same day, the FDA issued an announcement that stated in relevant part:

***FDA understands that the manufacturer of Makena, KV Pharmaceuticals, has sent letters to pharmacists indicating that FDA will no longer exercise enforcement discretion with regard to compounded versions of Makena. This is not correct.***

In order to support access to this important drug, at this time and under this unique situation, FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products. As always, FDA may at any time revisit a decision to exercise enforcement discretion.

38. As a result of this disclosure, the price of K-V's A series stock again dropped from \$7.11 to \$5.65 in a single trading session. This decrease in the price of K-V's stock was a result of more of the artificial inflation caused by defendants' misleading statements coming out of the price.

39. On April 1, 2011, defendants issued a press release that stated in relevant part:

As part of its ongoing efforts to ensure that high-risk women have access to FDA-approved Makena instead of unapproved, unregulated compounded drugs, Ther-Rx Corporation, a subsidiary of K-V Pharmaceutical Company (NYSE: KVa/KVb) (the "Company"), announced today important initiatives to reduce the cost of Makena™ (hydroxyprogesterone caproate injection) and encourage stakeholders to provide timely access to this important FDA-approved medication. Effective immediately, Ther-Rx has:

- Reduced the list price of Makena by nearly 55 percent, to \$690 per injection;
- Will offer supplemental rebates that, in conjunction with the list price reduction and the standard Medicaid rebate of 23.1 percent, will result in a substantially reduced cost per injection for state Medicaid agencies compared to list price. This will help ensure that every woman who is prescribed Makena – regardless of her ability to pay – has the comfort of knowing a medication that has been rigorously reviewed by FDA for safety and efficacy is available to her;
- Capped the costs for a full course of therapy to a maximum of three vials (15 injections) for contracted health insurance plans and state Medicaid agencies; and
- Expanded the Company's patient assistance program for patients who are prescribed this important medication by removing income caps to qualify for financial assistance. 85 percent of patients will pay \$20 or less per injection for FDA-approved Makena, and patients whose financial need is greatest would receive FDA-approved Makena at no out-of-pocket cost.

40. The final shoe fell on April 4, 2011, when *Bloomberg* published a story entitled "KV Pharma's Reduced Makena Price Won't Sway Some Physicians," that revealed, citing

detailed interviews with several physicians, even with the 55% Makena list price reduction, prescribing physicians would not recommend Makena to their patients. Quoting George Saade, professor and division chief of maternal-fetal medicine at the University of Texas, *Bloomberg* reported that “‘KV/A lowered the price but it is still too high,’ capped to 15 doses a pregnancy Makena could cost up to \$7000 after discounts to Medicaid and other items.” Arnold Cohen, professor and chairman of the department of OBGYN at Albert Einstein Medical Center in Philadelphia, told *Bloomberg* that the hostility generated by the initial Makena price had created a barrier to using K-V’s Makena as there was already a cheaper alternative available that the FDA stood behind, with Cohen emphasizing: “If I have a choice, let’s say this never happened and KV/A came out and said Makena is going to be priced at \$50 for an injection, I think most of us would have been ok with that.” *Bloomberg* also surmised that “[a]t current prices if a physician were to buy Makena, that physician would have to assume the responsibility for the inventory, as there is no guarantee a patient or an insurance company will pay for it,” citing Baha Sibai, professor of clinical obstetrics and gynecology at the University of Cincinnati.

41. On the final April 4th disclosure, K-V’s stock price was hammered and fell an additional 9.5% in a single trading session, closing down at \$5.39 on April 4, 2011 from its close of \$5.99 the prior evening. As the market further absorbed this news, the stock price suffered further erosion and now trades at less than \$2 per share. This decrease in the price of K-V’s stock was a result of the artificial inflation caused by defendants’ misleading statements coming out of the price.

42. Meanwhile, the artificial price inflation defendants’ false and misleading statements caused K-V’s securities to trade at during the Class Period enabled K-V to sell \$200 million worth of senior secured notes during the Class Period, used in large part to pay the Company’s debts.

#### **LOSS CAUSATION / ECONOMIC LOSS**

43. During the Class Period, as detailed herein, defendants made false and misleading statements and engaged in a scheme to deceive the market. This artificially inflated the price of

K-V's securities and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of K-V's securities fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of K-V securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

#### **NO SAFE HARBOR**

44. K-V's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

45. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of K-V who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

#### **APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET**

46. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) The omissions and misrepresentations were material;
- (c) The Company's securities traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

(e) Plaintiff and other members of the Class purchased K-V securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

47. At all relevant times, the market for K-V securities was efficient for the following reasons, among others:

(a) As a regulated issuer, K-V filed periodic public reports with the SEC; and

(b) K-V regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

#### **CLASS ACTION ALLEGATIONS**

48. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased the publicly traded securities of K-V during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of K-V and their families and affiliates.

49. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. K-V had more than 59 million shares outstanding, owned by thousands of persons.

50. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) whether the 1934 Act was violated by defendants;

(b) whether defendants omitted and/or misrepresented material facts;

(c) whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether defendants knew or recklessly disregarded that their statements were false and misleading;

(e) whether the prices of K-V securities were artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

51. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

52. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

53. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

#### COUNT I

##### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

54. Plaintiff incorporates ¶¶1-53 by reference.

55. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

56. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

(a) employed devices, schemes, and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of K-V securities during the Class Period.

57. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for K-V securities. Plaintiff and the Class would not have purchased K-V securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

58. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of K-V securities during the Class Period.

## COUNT II

### **For Violation of §20(a) of the 1934 Act Against All Defendants**

59. Plaintiff incorporates ¶¶1-58 by reference.

60. The individual defendants acted as controlling persons of K-V within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about K-V, the individual defendants had the power and ability to control the actions of K-V and its employees. K-V controlled the individual defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

Date: October 19, 2011

WALTERS, BENDER, STROHBEHN VAUGHAN, P.C.  
R. KEITH JOHNSTON

/s/ R. Keith Johnston

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**CERTIFICATION PURSUANT TO  
THE FEDERAL SECURITIES LAWS**

I, Frank Julianello, hereby certify that the following is true and correct to the best of my knowledge, information, and belief:

1. I have reviewed the Complaint against K-V Pharmaceuticals and retain Zeldes & Haeggquist, LLP and such co-counsel it deems appropriate to associate with, and authorize the filing of the Complaint and/or lead plaintiff appointment papers in this matter on my behalf.

2. I am willing to serve as a representative party on behalf of the Class (as defined in the Complaint), including providing testimony at deposition and/or trial, if necessary.

3. During the Class Period (as defined in the Complaint), I purchased and/or sold the security that is the subject of the Complaint as set forth on the attached Schedule A.

4. I did not acquire the securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in this or any other securities class action.

5. During the three-year period preceding the date of my signing this Certification, I did not seek to serve, nor have I served as a representative party or lead plaintiff on behalf of a class in any private action(s) arising under the Securities Act or the Exchange Act.

6. I will not accept any payment for serving as a representative of the class beyond my *pro rata* share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the Court.

7. I have made no transactions during the Class Period in the securities that are the subject of this action except those set forth in the attached Schedule A.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 14 day of October, 2011, at \_\_\_\_\_, \_\_\_\_\_.

  
\_\_\_\_\_  
FRANK JULIANELLO

