

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Federal and Drug Administration ("FDA") and Lehigh Valley Technologies, Inc. ("LVT") (collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

- A. LVT is a pharmaceutical company engaged in the development and commercialization of certain human drug products that is located in Allentown, Pennsylvania.
- B. Pharma-Med is a company located in Bethlehem, Pennsylvania.
- C. Pharma Research Software Solution, LLC ("PRSS") is an information technology company located in North Holland, Pennsylvania.
- D. FDA regulates the approval of new drugs. A company seeking such approval must submit and receive FDA approval of a new drug application ("NDA") before the drug may be marketed or sold in the United States. The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new drug for sale and marketing.
- E. Congress created the Prescription Drug User Fee Act ("PDUFA") in 1992 that authorizes and requires FDA to collect a "prescription drug user fee" or "application fee" from companies that submit an NDA. PDUFA gives the FDA a revenue source to fund the new drug approval process.

F. Under 21 U.S.C. § 379h(d)(1)(C), the FDA will grant a waiver of the fee to a small business applicant submitting its first application. In making that determination, the FDA must consider “any affiliate of the applicant,” including large businesses or businesses that have already received the fee waiver.

G. The purpose of the fee waiver, among other reasons, is to incentivize and level the playing field for small businesses who desire to submit an NDA. Limiting the waiver to first-time applicants allows a new, small business to enter the industry without the significant costs to entry that the NDA fee would otherwise impose.

H. The United States contends that it has certain civil claims against LVT arising from its avoidance of the NDA fee on two separate occasions. Although LVT disputes the contentions of the United States, specifically, the United States contends that:

1. LVT had previously received a fee waiver in 2010 for its Oxycodone Hydrochloride NDA because it was deemed to be a small business and first-time applicant.
2. Because it received that fee waiver, LVT was ineligible by law to receive another such fee waiver based on its designation as a small business.
3. LVT subsequently desired to submit two NDAs for potassium chloride for oral solution.
4. Had LVT submitted the NDAs in its own name, FDA would have required it to pay fees totaling \$2,252,150. Because it was not a first-

time applicant, however, LVT was ineligible for the fee waiver based on its designation as a small business.

5. Knowing that it was ineligible, LVT developed a plan to avoid the fee.
6. It first entered into an agreement with Pharma-Med in 2012 designed to circumvent paying the fee. Under the terms of the agreement, LVT paid Pharma-Med to submit the NDA for Potassium Chloride for Oral Solution (NDA No. 206814) in Pharma-Med's name. The payment was contingent upon FDA granting Pharma-Med a waiver from the prescription drug user fee. Had LVT submitted the NDA in its own name, FDA would have required it to pay a prescription drug user fee totaling \$1,084,550.
7. LVT prepared and controlled all of the submissions that Pharma-Med made to the FDA relating to the NDA approval.
8. Neither LVT nor Pharma-Med disclosed to the government the agreement between LVT and Pharma-Med despite the government's request for such information.
9. Not knowing of the agreement, FDA granted a fee waiver and approved the NDA in 2014.
10. Subsequently in 2013, LVT entered into a similar agreement with PRSS. Under the terms of the agreement, LVT paid PRSS to submit the NDA for Potassium Chloride for Oral Solution (NDA No. 208019) in PRSS' name. The payment was contingent upon FDA granting PRSS a waiver from the prescription drug user fee/application fee.

Had LVT submitted the NDA in its own name, FDA would have required it to pay a prescription drug user fee totaling \$1,167,600.

11. LVT prepared and controlled all of the submissions that PRSS made to the FDA relating to the NDA approval.
12. Neither LVT nor PRSS disclosed to the government the agreement between LVT and PRSS despite the government's request for such information.
13. Not knowing of the agreement, FDA granted a fee waiver and approved the NDA in 2015.
14. The sole purpose of the arrangement with Pharma-Med and PRSS was for those companies to serve as a front and allow LVT to avoid the FDA fees that FDA otherwise would have required it to pay. PRSS and Pharma-Med's involvement served no other purpose and, indeed, those companies had no knowledge or expertise about potassium chloride for oral solution or their obligations as a drug sponsor.

I. The United States contends that it has certain civil claims against LVT arising from the two NDAs for Potassium Chloride for Oral Solution discussed above. By submitting the NDAs through Pharma-Med and PRSS and not disclosing the arrangement to the government, LVT avoided paying to the FDA the prescription drug user fees during the NDA application process from 2012 through 2016 totaling \$2,252,150. That conduct is referred to below as the "Covered Conduct."

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. LVT shall pay to the United States \$4,000,000 (Four Million Dollars) (“the Settlement Amount”), of which \$2,000,000 (Two Million Dollars) is restitution. LVT shall pay the Settlement Amount plus interest accruing thereon from December 4, 2018, at an annual rate of 4% (compounding daily). LVT shall pay the Settlement Amount by electronic funds transfer pursuant to written instructions to be provided by United States Attorney’s Office for the Eastern District of Pennsylvania. LVT shall pay in two installments: \$2,000,000 within ten days of the Effective Date and the remaining Settlement plus interest within 9 months of the Effective Date. This Agreement is neither an admission of liability or wrongdoing by the Defendants nor a concession by the United States that its claims are not well-founded.

2. Subject to the exceptions in Paragraph 3 (concerning excluded claims) below, and conditioned upon LVT’s full payment of the Settlement Amount, the United States releases LVT from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

3. Notwithstanding the release given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in this Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability of individuals.

4. LVT waives and shall not assert any defenses LVT may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action.

5. LVT fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that LVT has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of LVT, and its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) LVT's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement;
- (5) the payment LVT makes to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by LVT, and LVT shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, LVT shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by LVT or any of its subsidiaries or affiliates

from the United States. LVT agrees that the United States, at a minimum, shall be entitled to recoup from LVT any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine LVT's books and records and to disagree with any calculations submitted by LVT or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by LVT, or the effect of any such Unallowable Costs on the amount of such payments.

7. LVT agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, LVT shall encourage, and agrees not to impair, the cooperation of its directors, officers, and employees, and shall use its best efforts to make available, and encourage, the cooperation of former directors, officers, and employees for interviews and testimony, consistent with the rights and privileges of such individuals. LVT further agrees to furnish to the United States, upon request, complete and unredacted copies of all non-privileged documents, reports, memoranda of interviews, and records in its possession, custody, or control concerning any investigation of the Covered Conduct that it has undertaken, or that has been performed by another on its behalf.

8. This Agreement is intended to be for the benefit of the Parties only.

9. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

10. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

11. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the Eastern District of Pennsylvania. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

13. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

14. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

15. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

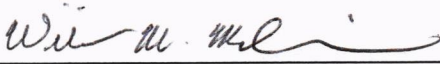
16. This Agreement is binding on LVT's successors, transferees, heirs, and assigns.

17. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

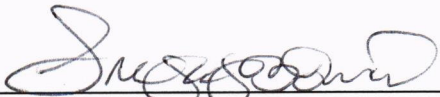
18. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 2/4/19

BY: 
WILLIAM M. McSWAIN
United States Attorney

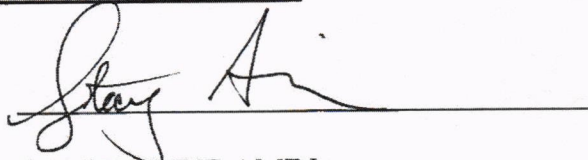
DATED: 2/22/19

BY: 
GREGORY B. DAVID
Assistant United States Attorney
Chief, Civil Division

FOOD AND DRUG ADMINISTRATION

DATED: 2-13-2019

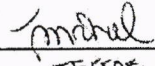
BY:

A handwritten signature in black ink, appearing to read "Stacy A.", is written over a horizontal line.

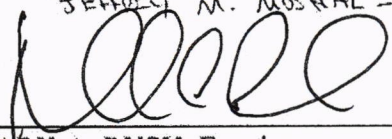
STACY CLINE AMIN
Chief Counsel

LEHIGH VALLEY TECHNOLOGIES, INC.

DATED: February 21, 2019

BY: 
JEFFREY M. MOSKAL - CEO

DATED: FEB 22, 2019

BY: 
MARK A. RUSH, Esquire
Counsel for LVT