

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is entered into among the United States of America, acting through the United States Department of Justice and acting on behalf of the Office of Inspector General of the Department of Health and Human Services (collectively, the “United States”), Zyno Medical, LLC (“Zyno Medical” or “Zyno”), and John Bertucci and Lowell Warner (the “relators”) (hereafter collectively referred to as “the Parties”), through their authorized representatives.

RECITALS

A. During the relevant time period, Zyno Medical designed, manufactured, and distributed intravenous (“IV”) infusion pumps and medical administration sets. Zyno Medical’s headquarters are in Natick, Massachusetts.

B. On February 26, 2020, John Bertucci and Lowell Warner filed a qui tam action in the United States District Court for the District of Massachusetts captioned *United States ex rel. Bertucci, et al. v. Zyno Medical, LLC, et al.*, No. 20-cv-10388-WGY, pursuant to the qui tam provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the “Civil Action”). The relators allege in the Civil Action, among other things, that Zyno caused the submission of false claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395lll (“Medicare”), by causing the submission of claims for administration of medication through devices Zyno Medical knew were defective.

C. The United States contends that Zyno Medical submitted or caused to be submitted claims for payment to Medicare.

D. Zyno Medical admits, acknowledges, and accepts its responsibility for the following facts. As early as November 5, 2015, Zyno knew that certain of its medical administration sets, which it sold to be used with its Z-800 series IV infusion pumps, were

defective, that the defect had caused leaks during the infusion of medication, and that the defect had the potential to cause such leaks during future infusion treatments. Zyno did not recall the affected medical administration sets and, in fact, for a certain period continued to sell affected medical administration sets. On July 29, 2016, Zyno finally issued a recall notice to its customers. That conduct is referred to below as the “Covered Conduct.”

E. The United States contends that it has certain civil claims against Zyno Medical arising from the Covered Conduct, which resulted in Zyno causing the submission of false claims to Medicare, in violation of the False Claims Act.

F. The relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to the relators’ reasonable expenses, attorneys’ fees, and costs.

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. Zyno Medical shall pay to the United States \$493,140 (the “Settlement Amount”), plus interest on the Settlement Amount accruing at an annual rate of 4.0% from October 3, 2022. Zyno Medical shall make payment of the Settlement Amount no later than 10 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney for the District of Massachusetts. Of the Settlement Amount, \$246,570 is restitution.

2. Conditioned upon the United States receiving the Settlement Amount, and as soon as feasible after receipt, the United States shall pay \$98,628 to the relators by electronic funds transfer (the “Relators’ Share”).

3. Zyno Medical shall pay to the relators the amount of \$476,227.24, as full satisfaction of the relators' claims against Zyno Medical for the relators' attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d). The terms and releases related to the settlement of the relators' attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d) are not provided for herein but are instead the subject of a separate agreement between Zyno Medical and the relators.

4. Subject to the exceptions in Paragraph 6 (concerning reserved claims) below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the United States releases Zyno Medical 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 Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812 or the common law theories of payment by mistake, unjust enrichment, and fraud.

5. Subject to the exceptions in Paragraph 6 below, and upon the United States' receipt of the Settlement Amount, plus interest due under Paragraph 1, the relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, releases Zyno Medical from any civil monetary claim the relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

6. Notwithstanding the releases given in Paragraph 4 of this Agreement, or any other term of this Agreement, the following claims and rights 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 or enforcement right, including mandatory or permissive exclusion from Federal health care programs;
- 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;
- g. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- h. Any liability for failure to deliver goods or services due; and
- i. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct.

7. The relators and their heirs, successors, attorneys, agents, and assigns do not object to this Agreement and agree and confirm that this Agreement is fair, adequate, and reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B). Conditioned upon the relators' receipt of the Relators' Share, the relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

8. The relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release Zyno Medical, and its officers, agents, and employees, from any liability to the relators arising from the filing of the Civil Action.

9. Zyno Medical waives and shall not assert any defenses Zyno Medical 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.

10. Zyno Medical fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Zyno Medical 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 or the United States' investigation or prosecution thereof.

11. Zyno Medical fully and finally releases the relators from any claims (including attorneys' fees, costs, and expenses of every kind and however denominated) that Zyno Medical has asserted, could have asserted, or may assert in the future against the relators, related to the Covered Conduct and the relators' investigation and prosecution thereof.

12. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Zyno Medical agrees not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agrees not to appeal any such denials of claims, and agrees to withdraw any such pending appeals.

13. Zyno Medical agrees to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395lll and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Zyno Medical, 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 and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Zyno Medical's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorneys' fees);
- (4) the negotiation and performance of this Agreement; and
- (5) the payment Zyno Medical makes to the United States pursuant to this Agreement and any payments that Zyno Medical may make to the relators, including costs and attorneys fees

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Zyno Medical, and Zyno Medical shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost

statement, information statement, or payment request submitted by Zyno Medical or any of its subsidiaries or affiliates to the Medicare, Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Zyno Medical further agrees that within 90 days of the Effective Date of this Agreement it shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Zyno Medical or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the Unallowable Costs. Zyno Medical agrees that the United States, at a minimum, shall be entitled to recoup from Zyno Medical any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Zyno Medical or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this paragraph) on Zyno Medical or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Zyno Medical's books and records to determine

that no Unallowable Costs have been claimed in accordance with the provisions of this paragraph.

14. Zyno Medical agrees to cooperate fully and truthfully with the United States' investigation of individuals and entities not released in this Agreement. Upon reasonable notice, Zyno Medical 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. Zyno Medical 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.

15. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 16 (waiver for beneficiaries paragraph), below.

16. Zyno Medical agrees that it waives and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third-party payors based upon the claims defined as Covered Conduct.

17. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action pursuant to Rule 41(a)(1).

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

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

20. 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 District of Massachusetts. 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.

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

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

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

24. This Agreement is binding on Zyno Medical's successors, transferees, heirs, and assigns.

25. This Agreement is binding on the relators' successors, transferees, heirs, and assigns.

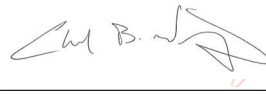
26. All Parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

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

THE UNITED STATES OF AMERICA

DATED: _____


BY: _____



Digitally signed by CHARLES WEINOGRAD
Date: 2022.12.23 16:01:06 -05'00'

Charles B. Weinograd
Assistant United States Attorney
District of Massachusetts

**JOANNA
PERSIO**



Digitally signed by JOANNA PERSIO
Date: 2022.12.23 12:47:18 -05'00'

Joanna G. Persio
Trial Attorney
Department of Justice

Zyno Medical, LLC - DEFENDANT

DATED: _____

BY: _____

Chao Young Lee
President

DATED: _____

BY: _____

Robert Fisher
Counsel for Zyno Medical

RELATORS

DATED: _____

BY: _____

John Bertucci

DATED: _____

BY: _____

Lowell Warner

DATED: _____

BY: _____

Jonathan Shapiro
Shapiro & Teitelbaum LLP
Counsel for the Relators

Sherif K. Sakla, M.D., J.D.
The Sakla Law Firm, APLC
Counsel for the Relators

Gary L. Azorsky
Cohen Milstein Sellers & Toll PLLC
Counsel for the Relators

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____


Charles B. Weinograd
Assistant United States Attorney
District of Massachusetts

Joanna G. Persio
Trial Attorney
Department of Justice

Zyno Medical, LLC - DEFENDANT

DATED: _____

BY: _____


Chao Young Lee
~~President~~ CEO

DATED: _____

BY: _____

Robert Fisher
Counsel for Zyno Medical

RELATORS

DATED: _____

BY: _____

John Bertucci

DATED: _____

BY: _____

Lowell Warner

DATED: _____

BY: _____

Jonathan Shapiro
Shapiro & Teitelbaum LLP
Counsel for the Relators

Sherif K. Sakla, M.D., J.D.
The Sakla Law Firm, APLC
Counsel for the Relators

Gary L. Azorsky
Cohen Milstein Sellers & Toll PLLC
Counsel for the Relators

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Charles B. Weinograd
Assistant United States Attorney
District of Massachusetts

Joanna G. Persio
Trial Attorney
Department of Justice

Zyno Medical, LLC - DEFENDANT

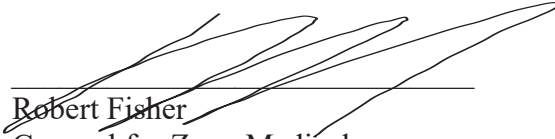
DATED: _____

BY: _____

Chao Young Lee
President

DATED: _____

BY: _____


Robert Fisher
Counsel for Zyno Medical

RELATORS

DATED: _____

BY: _____

John Bertucci

DATED: _____

BY: _____

Lowell Warner

DATED: _____

BY: _____

Jonathan Shapiro
Shapiro & Teitelbaum LLP
Counsel for the Relators

Sherif K. Sakla, M.D., J.D.
The Sakla Law Firm, APLC
Counsel for the Relators

Gary L. Azorsky
Cohen Milstein Sellers & Toll PLLC
Counsel for the Relators

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Charles B. Weinograd
Assistant United States Attorney
District of Massachusetts

Joanna G. Persio
Trial Attorney
Department of Justice

Zyno Medical, LLC - DEFENDANT

DATED: _____

BY: _____

Chao Young Lee
President

DATED: _____

BY: _____

Robert Fisher
Counsel for Zyno Medical

RELATORS

DATED: _____

BY: _____

John Bertucci

DATED: 12-23-22

BY:  _____

Lowell Warner

DATED: _____

BY: _____

Jonathan Shapiro
Shapiro & Teitelbaum LLP
Counsel for the Relators

Sherif K. Sakla, M.D., J.D.
The Sakla Law Firm, APLC
Counsel for the Relators

Gary L. Azorsky
Cohen Milstein Sellers & Toll PLLC
Counsel for the Relators

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

Charles B. Weinograd
Assistant United States Attorney
District of Massachusetts

Joanna G. Persio
Trial Attorney
Department of Justice

Zyno Medical, LLC - DEFENDANT

DATED: _____

BY: _____

Chao Young Lee
President

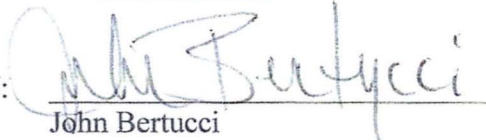
DATED: _____

BY: _____

Robert Fisher
Counsel for Zyno Medical

RELATORS

DATED: 12/23/22

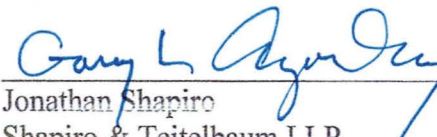
BY: 
John Bertucci

DATED: _____

BY: _____

Lowell Warner

DATED: 12/23/22

BY: 
Jonathan Shapiro
Shapiro & Teitelbaum LLP
Counsel for the Relators

Sherif K. Sakla, M.D., J.D.
The Sakla Law Firm, APLC
Counsel for the Relators

Gary L. Azorsky
Cohen Milstein Sellers & Toll PLLC
Counsel for the Relators