

IN THE DISTRICT COURT OF DOUGLAS COUNTY, NEBRASKA

**STATE OF NEBRASKA, ex rel.
DOUGLAS J. PETERSON, ATTORNEY
GENERAL,**

Plaintiff,

v.

**PIVOT CONCIERGE HEALTH, LLC;
and
BANYAN MEDICAL SYSTEMS, LLC,**

Defendants.

Case No: CI 20 – 5231

**ASSURANCE OF
DISCONTINUANCE**

WHEREAS, the State of Nebraska, ex rel. Douglas J. Peterson, Nebraska Attorney General, by and through the undersigned Assistant Attorney General (hereinafter "Attorney General", "State", or "Plaintiff"), has filed a Complaint against Defendant Pivot Concierge Health, LLC and Defendant Banyan Medical Systems, LLC (hereinafter collectively "Defendants") requesting an injunction and other relief in this matter pursuant to the Consumer Protection Act, Neb. Rev. Stat. § 59-1601 *et seq.* (hereinafter "CPA" or "Consumer Protection Act") and the Uniform Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-301 *et seq.* (hereinafter "UDTPA" or "Uniform Deceptive Trade Practices Act"), alleging Defendants committed violations of the CPA and UDTPA in connection with their Advertising, Marketing, distribution, and sale of COVID-19 Products and Services; and

WHEREAS, Defendants deny any violations of law, including violations of the CPA or UDTPA, and deny that the Plaintiff is entitled to an injunction; and

WHEREAS, for the convenience of the parties and to avoid the time, expense, and uncertainty of litigation, Plaintiff and Defendant have consented to entry by the Court of this Assurance of Discontinuance (hereinafter “Assurance”) pursuant to Neb. Rev. Stat. §§ 59-1610 and 87-303.05 without trial or adjudication of any issue of fact or law, and without finding or admission of wrongdoing. Plaintiff and Defendant agree to entry of an Order Approving this Assurance to avoid the expenses associated with further investigation or litigation. Defendant agrees to be bound by the terms of this Assurance.

NOW THEREFORE, upon the consent of the Parties hereto, **IT IS HEREBY AGREED AS FOLLOWS:**

PARTIES

1. Plaintiff, Douglas J. Peterson, is the duly elected, qualified, and acting Attorney General of the State of Nebraska. The Attorney General is responsible for enforcement of Nebraska consumer protection laws, including, but not limited to, the Consumer Protection Act and the Uniform Deceptive Trade Practices Act.

2. Defendant Pivot Concierge Health, LLC (hereinafter "Pivot"), is a Nebraska limited liability company with its principal place of business at 2801 S 88th Street, Omaha, NE 68124. At all times relevant hereto, Pivot engaged in trade or commerce in the state of Nebraska by providing healthcare services within Nebraska and to Nebraska consumers, including by Advertising, Marketing, distributing, and selling COVID-19 Testing Products and Services.

3. Defendant Banyan Medical Systems, LLC (hereinafter "Banyan"), is a Nebraska limited liability company with its principal place of business at 8701 F Street, Omaha, NE 68127. At all times relevant hereto, Banyan engaged in trade or commerce in the state of Nebraska by providing healthcare services within Nebraska and to Nebraska consumers, including by Advertising, Marketing, distributing, and selling COVID-19 Testing Products and Services.

JURISDICTION & VENUE

4. The District Court of Douglas County has jurisdiction over Defendants and the subject matter of this action pursuant to Neb. Rev. Stat. § 59-1608 and Neb. Rev. Stat. § 87-303.05(1) because Defendants have transacted business within the State of Nebraska at all times relevant to this Complaint.

5. Venue for this action properly lies in the District Court of Douglas County pursuant to Neb. Rev. Stat. § 59-1608.01 and Neb. Rev. Stat. § 87-303.05(1) because Defendants have transacted business in Douglas County, Nebraska.

INTRODUCTION

6. There is currently a pandemic of respiratory disease caused by a novel coronavirus. The virus has been named "severe acute respiratory syndrome coronavirus 2" (SARS-CoV-2) and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19).¹

DEFINITIONS

The following definitions shall be used in construing this Assurance:

7. “**Advertise**” or “**Advertising**” shall mean any oral, written, graphic, or pictorial statement or representation, including but not limited to testimonials, endorsements, or other third party representations, regardless of the medium of communication employed, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase or use of any product or service.

8. “**Clearly and Conspicuously**” shall mean a statement that, regardless of the medium in which it is made, is readily understandable and presented in such size, color, contrast, duration and location, compared to the other information with which it is presented, that it is readily apparent, readable and understandable. A statement may not contradict or be inconsistent with any other information with which it is presented.

9. “**COVID-19 Testing Products and Services**” shall mean products and services intended to screen for, diagnose, detect, identify, or inform infection status of SARS-CoV-2, including but not

¹ The SARS-CoV-2 virus is referred to throughout this Assurance as either “SARS-CoV-2” or “COVID-19”.

limited to molecular tests (i.e., detect SARS-CoV-2 nucleic acids from human specimens), antigen tests (i.e., detect SARS-CoV-2 antigens directly from clinical specimens), serological tests (i.e., identify antibodies to SARS-CoV-2 from clinical specimens), and any other product or service Advertised, Marketed, distributed, or sold by Defendants for the purpose of administering the aforementioned tests or diagnosing any disease or condition related to COVID-19.

10. “**Defendants**” shall mean Defendant Banyan and Defendant Pivot, individually, collectively, or in any combination.

11. “**Defendant Banyan**” shall mean and include Banyan Medical Systems, LLC, and all of its directors, officers, employees, agents, subsidiaries, parent or controlling entities, and any assigns or successor corporation or business entities.

12. “**Defendant Pivot**” shall mean and include Pivot Concierge Health, LLC, and all of its directors, officers, employees, agents, subsidiaries, parent or controlling entities, and any assigns or successor corporation or business entities.

13. “**Effective Date**” shall mean the date on which this Assurance, duly executed by the Parties, is approved by the Court, pursuant to a Final Consent Judgment of the Court.

14. “**Market**” or “**Marketing**” shall mean any act or process or technique of promoting, offering, selling, or distributing a COVID-19 Testing Product or Service.

15. “**Marketing Materials**” shall mean any written, electronic, or verbal material or statements either publicly disseminated (including videos, websites it hosts or controls, or any other form of media) or made for the purpose of public dissemination in the United States, in the course of Marketing, promoting, or informing health care providers, consumers, or patients about any COVID-19 Testing Product and Service.

16. “**Parties**” shall mean the State of Nebraska, Defendant Pivot, and Defendant Banyan.

17. Unless otherwise defined, terms in this Assurance shall be construed consistent with the Consumer Protection Act and the Uniform Deceptive Trade Practices Act.

ASSURANCES

18. Defendants shall not engage in unfair or deceptive acts or practices, in violation of the Consumer Protection Act and the Uniform Deceptive Trade Practices Act, in the course of Advertising, Marketing, distribution, or sale of any COVID-19 Testing Product and Service.

19. Defendants shall, at the time Defendants Advertise, Market, distribute, or sell any COVID-19 Testing Product and Service, Clearly and Conspicuously disclose to consumers:

- (a) all material facts, including all known risks and limitations of each COVID-19 Testing Product and Service Advertised, Marketed, distributed, or sold; and
- (b) all material information related to each COVID-19 Testing Product and Service, if such information was provided to Defendants by the manufacturer of the COVID-19 Testing Product and Service.

20. Defendants shall not misrepresent, in any manner, expressly or by implication, the characteristics of any COVID-19 Testing Product and Service Advertised, Marketed, distributed, or sold by Defendants.

21. Defendants shall, in the Advertising, Marketing, and promotion of any COVID-19 Testing Product and Service, ensure that their Marketing Materials and other communications do not misrepresent FDA updates, communications, or guidance documents regarding COVID-19.

22. Defendants shall not, in any Marketing Materials, misrepresent the FDA approval or clearance status of any COVID-19 Testing Product and Service.

23. Defendants shall ensure that their independent contractors, agents, and employees, who Advertise, Market, distribute, or sell any COVID-19 Testing Product and Service or otherwise train, provide information to, or communicate with consumers about any COVID-19 Testing Product and Service, are adequately informed and trained regarding FDA regulation, policy, and guidance.

24. Plaintiff shall be permitted reasonable access to inspect and copy relevant, non-privileged, non-work product records and documents in the possession, custody, or control of Defendants that directly relate to Defendants' compliance with each provision of this Assurance.

25. Defendants shall, for three (3) years after the Effective Date, deliver a copy of this Assurance to all principals, officers, and directors, as well as all employees having managerial responsibilities for Advertising or Marketing Defendants' products or services. Delivery must occur within ten (10) days after the Effective Date for current personnel. For all others, delivery must occur before they assume their responsibilities.

26. Defendants shall not participate in any activity to form, organize, or reorganize into a separate entity or corporation which engages in acts or practices in whole or in part that are prohibited by this Assurance or for any other purpose that would otherwise circumvent any term of this Assurance. Defendants shall not knowingly cause, permit, or encourage any other persons or entities acting on their behalf to engage in practices prohibited by this Assurance.

27. Defendants shall generate and retain all material records and documents reasonably necessary to document compliance with this Assurance.

PAYMENT & ENFORCEMENT

28. No later than thirty (30) days after the Effective Date, Defendant Pivot shall pay twenty five thousand dollars (\$25,000.00) to Plaintiff which will be placed in the State Settlement Cash Fund and may be used for purposes that may include, but are not limited to, attorneys' fees and other costs of investigation, future consumer protection enforcement, consumer education, litigation, to defray the costs of the inquiry leading hereto, or for other uses permitted by state law at the sole discretion of the Nebraska Attorney General.

29. Defendants shall pay to Plaintiff all court costs and reasonable attorneys' fees associated with any successful Complaint or other filing by Plaintiff to enforce any provision of this Assurance against Defendants in the future.

GENERAL PROVISIONS

30. This Assurance is effective upon the date on which this Assurance, duly executed by the Parties, is approved by the Court, pursuant to an Order of the Court ("Effective Date").

31. Nothing in this Assurance shall be considered an admission of wrongdoing or a violation of law for any purpose.

32. Nothing in this Assurance shall be construed so as to limit or bar any other person or entity from pursuing any and all available legal remedies against Defendants; nor is it the intent of the Parties hereto that this Assurance shall create or support a cause of action against Defendants by non-parties to this Assurance.

33. Unless otherwise provided under state law, no part of this Assurance is intended to create a private cause of action or confer any right to any third party for violation of any federal or state statute except that Plaintiff may file an action to enforce the terms of this Assurance.

34. Nothing in this Assurance shall be construed to limit the authority or ability of Plaintiff to protect the interest of the State or people of Nebraska. Further, nothing contained in this Assurance shall be construed to limit the ability of Plaintiff to enforce the obligations that Defendants have under this Assurance. This Assurance shall not bar Plaintiff or any other governmental entity from enforcing laws, regulations, or rules against Defendants for conduct subsequent to or otherwise not covered by this Assurance.

35. Nothing in this Assurance shall be construed as relieving Defendants of the obligation to comply with any and all federal, state, and local laws, regulations, or rules, nor shall any of the provisions of this Assurance be deemed a waiver or permission to engage in any act or practice prohibited by law, regulation, or rule.

36. Nothing in this Assurance shall be construed to prohibit Defendants from making representations with respect to any product or service in labeling that are required under federal law, regulations, or polices or guidance having the force of law, including in Food and Drug Administration (“FDA”) approved labeling.

37. Nothing in this Assurance shall be construed to prohibit, limit, or restrict the lawful communications and consultations between Defendants’ licensed healthcare professionals and individual

patients regarding such individual patients' healthcare decisions, including the testing, diagnosis or treatment of COVID-19 in individual patients.

38. This Assurance shall not be construed as an approval of or sanction by Plaintiff of Defendants' practices, nor shall Defendants represent the Assurance as such approval or sanction. The Parties further understand and agree that any failure by Plaintiff to take any action in response to any information submitted pursuant to this Assurance shall not be construed to be an approval of or sanction of any representations, acts, or practices of Defendants, nor shall any inaction by Plaintiff be considered a waiver by Plaintiff of any rights under this Assurance or the law.

39. The headings in this Assurance are used for the purpose of convenience only and are not intended to affect the interpretation or construction of this Assurance.

40. Neither party shall be deemed the drafter of this Assurance and, in construing this Assurance, no provision hereof shall be construed in favor of one party on the ground that such provision was drafted by the other.

41. If any portion, provision, or part of this Assurance is held to be invalid, unenforceable or void for any reason whatsoever, that portion shall be severed from the remainder and shall not affect the validity or enforceability of the remaining provisions, portions, or parts.

42. The Parties acknowledge and represent that: (a) each Party has read this Assurance in its entirety and fully understands all of its terms and conditions and the ramifications and consequences thereof; (b) each Party unconditionally consents to the terms of this Assurance; (c) each Party has either consulted with or had ample opportunity to consult with legal counsel of its choosing prior to executing this Assurance; (d) each Party has freely and voluntarily signed this Assurance; and (e) the consideration received by each Party as described in this Assurance is adequate.

43. This Assurance contains the entire understanding of the Parties and supersedes and forever terminates all prior and contemporaneous representations, promises, agreements, understandings, and negotiations, whether oral or written, with respect to its subject matter. The Parties further agree that this

Assurance may only be amended, modified, or supplemented by a duly executed writing signed by each Party to this Assurance and approved by the Court.

44. This Assurance may be executed by any number of counterparts, each of which shall be deemed an original hereof, but which together shall constitute one and the same instrument and agreement, and that facsimile or electronically-transmitted signatures may be attached to this Assurance and shall be binding on such Party as an original signature.

WHEREFORE, each undersigned representative of Plaintiff and Defendants certify that he or she is fully authorized to enter into this Assurance and legally bind such Party to its terms. The following signatures are affixed hereto as of the dates written below in agreement hereof.

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JOINTLY APPROVED FOR ENTRY AND SUBMITTED BY:

FOR PLAINTIFF, STATE OF NEBRASKA:

THE STATE OF NEBRASKA, ex rel.
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3/22/21
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