~~**What is claimed is:**~~

## CLAIMS

1. A single-use, pre-primed device adapted for nasal delivery of a pharmaceutical ~~formulation for intranasal administration comprising, in~~ composition to a patient by one actuation of said device into one nostril of said patient, having a single reservoir comprising a pharmaceutical composition which is an aqueous solution of ~~not more than 140 µL:~~ about 100 µL comprising:

about 4 mg naloxone hydrochloride or a hydrate thereof;

~~1.~~ between about 0.2 mg and about 1.2 mg of an isotonicity agent; ~~between about 0.005 mg and about 0.015 mg of a preservative; between about 0.1 mg and about 0.5 mg of a stabilizing agent; and an acid sufficient to achieve a pH of 3.5-5.5.~~

~~A pharmaceutical formulation for intranasal administration comprising, in an aqueous solution of not more than 140 µL: about 2 mg naloxone hydrochloride or a hydrate thereof; between about 0.2 mg and about 1.2 mg of an isotonicity agent;~~ between about 0.005 mg and about 0.015 mg of a preservative; ~~between~~

about 0.~~1 mg and about 0.5~~2 mg of a stabilizing agent;

~~2.~~ an amount of an acid sufficient to achieve a pH of 3.5-5.5.

2. The ~~pharmaceutical formulation of~~ device as recited in claim 1 ~~or 2,~~ wherein:

the isotonicity agent is NaCl;

~~3.~~ the preservative is benzalkonium chloride; ~~and~~

the stabilizing agent is disodium edetate~~.~~; and

~~4. The pharmaceutical formulation of claim 1 wherein the aqueous solution comprises:~~

~~about 4 mg naloxone hydrochloride;~~

~~about 0.74 mg NaCl;~~

~~about 0.01 mg benzalkonium chloride; and~~

~~about 0.2 mg disodium edetate.~~

~~The pharmaceutical formulation of~~ the acid is hydrochloric acid.

~~5.~~ 3. The device of claim 2, wherein the aqueous solution comprises: ~~about 2 mg naloxone hydrochloride; about 0.74 mg NaCl; about 0.01 mg benzalkonium chloride; and~~

about 4.4 mg naloxone hydrochloride dihydrate;

about 0.74 mg NaCl;

about 0.01 mg benzalkonium chloride;

about 0.2 mg disodium edetate~~.~~; and

~~The pharmaceutical formulation of any one of claims 1 to 5~~an amount of hydrochloric acid sufficient to achieve a pH of 3.5-5.5.

4. The device of claim 2, wherein said device is actuatable with one hand.

~~6.~~ 5. The device of claim 4, wherein the ~~acid is hydrochloric acid~~volume of said reservoir is not more than about 140 µL.

6. The device of claim 5, wherein about 100 µL of said aqueous solution in said reservoir is delivered to said patient in one actuation.

7. The device of claim 6, wherein the pharmaceutical ~~formulation of any one of claims 1 to 6,~~composition which ~~yields a~~ is an aqueous solution comprises about 4.4 mg naloxone hydrochloride dihydrate.

8. The device of claim 7, wherein the 90% confidence interval for dose delivered per actuation is ±about 2%.

9. The device of claim 7, wherein the 95% confidence interval for dose delivered per actuation is ±about 2.5%.

10. The device of claim 7, wherein the delivery time is less than about 25 seconds.

11. The device of claim 7, wherein the delivery time is less than about 20 seconds.

12. The device of claim 7, wherein upon nasal delivery of said pharmaceutical composition to said patient, less than about 20% of said pharmaceutical composition leaves the nasal cavity via drainage into the nasopharynx or externally.

13. The device of claim 12, wherein upon nasal delivery of said pharmaceutical composition to said patient, less than about 10% of said pharmaceutical composition leaves the nasal cavity via drainage into the nasopharynx or externally.

14. The device of claim 13, wherein upon nasal delivery of said pharmaceutical composition to said patient, less than about 5% of said pharmaceutical composition leaves the nasal cavity via drainage into the nasopharynx or externally.

15. The device of claim 7, wherein the plasma concentration ~~of >=~~versus time curve of said naloxone hydrochloride in said patient has a $T_{max}$ of between about 20 and about 30 minutes.

16. The device of claim 1, wherein said patient is an opioid overdose patient or a suspected opioid overdose patient.

17. The device of claim 16, wherein the patient exhibits one or more symptoms chosen from: respiratory depression, central nervous system depression, cardiovascular depression, altered level consciousness, miotic pupils, hypoxemia, acute lung injury, aspiration pneumonia, sedation, hypotension, unresponsiveness to stimulus, unconsciousness, stopped breathing; erratic or stopped pulse, choking or gurgling sounds, blue or purple fingernails or lips, slack or limp muscle tone, contracted pupils, and vomiting.

18. The device of claim 17, wherein the patient exhibits respiratory depression.

19. The device of claim 18, wherein said respiratory depression is caused by the illicit use of opioids, or by an accidental misuse of opioids during medical opioid therapy.

20. The device of claim 19, wherein said patient is free from respiratory depression for at least about 1 hour following treatment comprising essentially of delivery of said therapeutically effective amount of said opioid antagonist.

21. The device of claim 20, wherein said patient is free from respiratory depression for at least about 2 hours following treatment comprising essentially of delivery of said therapeutically effective amount of said opioid antagonist.

22. The device of claim 21, wherein said patient is free from respiratory depression for at least about 4 hours following treatment comprising essentially of delivery of said therapeutically effective amount of said opioid antagonist.

23. The device of claim 22, wherein said patient is free from respiratory depression for at least about 6 hours following treatment comprising essentially of delivery of said therapeutically effective amount of said opioid antagonist.

24. The device of claim 16, wherein said patient is in a lying, supine, or recovery position.

~~7.~~ 25. The device of claim 7, wherein said single actuation yields a plasma concentration of ≧0.2 ng/mL within 2.5 minutes ~~of~~in said ~~intranasal administration~~patient.

~~8.~~ 26. The ~~pharmaceutical formulation~~device of ~~any one of claims 1 to 6, which~~ claim 7, wherein said single actuation yields a ~~naloxone~~ plasma concentration of ~~>=~~≧1 ng/mL within 5 minutes ~~of~~in said ~~intranasal administration~~patient.

~~9.~~ 27. The ~~pharmaceutical formulation~~device of ~~any one of claims 1 to 6, which~~ claim 7, wherein said single actuation yields a ~~naloxone~~ plasma concentration of ~~>=~~≧3 ng/mL within 10 minutes ~~of~~in said ~~intranasal administration~~patient.

~~10.~~ 28. The ~~pharmaceutical formulation~~device of ~~any one claims 1 to 9, which~~ claim 3, wherein said single actuation yields~~,~~ a ~~naloxone $T_{max}$~~plasma concentration of ~~less than 30~~≧0.2 ng/mL within 2.5 minutes in said patient.

~~11.~~ 29. The ~~pharmaceutical formulation~~device of ~~-~~ claim ~~10, which~~3, wherein said single actuation yields a ~~naloxone $T_{max}$~~plasma concentration of ~~less than 25~~≧1 ng/mL within 5 minutes in said patient.

~~12. The pharmaceutical formulation of claim 11, which yields a naloxone $T_{max}$ of less than 20 minutes.~~