Devices, Systems, and Methods for Medicament Delivery

Cross-References to Related Applications

[1] This application claims priority to, and incorporates by reference herein in its entirety, the following pending United States Provisional Patent Applications:

[2] Serial No. 60/648,822 (Attorney Docket No. 1022-010), filed 1 February 2005; and

[3] Serial No. 60/731,886 (Attorney Docket No. 1022-021), filed 31 October 2005.

Brief Description of the Drawings

[4] A wide variety of potential embodiments will be more readily understood through the following detailed description of certain exemplary embodiments, with reference to the accompanying exemplary drawings in which:

[5] **FIG. 1** is a perspective view of an exemplary embodiment of a system 1000;

[6] **FIG. 2** is a front view of an exemplary embodiment of a system 1000;

[7] **FIG. 3** is a side view of an exemplary embodiment of a system 1000;

[8] **FIG. 4** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 1000 in a first operative position;

[9] **FIG. 5** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 1000 in a second operative position;

[10] **FIG. 6** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 1000 in a third operative position;

[11] **FIG. 7** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 1000 in a fourth operative position;

[12] **FIG. 8** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 1000 in a fifth operative position;

[13] **FIG. 9** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 1000 in a sixth operative position;

[14] **FIG. 10** is a flowchart of an exemplary embodiment of a method 10000;

[15] **FIG. 11** is a perspective view of an exemplary embodiment of system 1000;

[16] **FIG. 12** is a perspective cross-sectional view taken along lines B-B of FIG. 11;

[17] **FIG. 13** is a perspective view of an exemplary embodiment of actuation stick 2200;

[18] **FIG. 14** is a cross-sectional view of an exemplary embodiment of gas venting mechanism 8000 taken along lines A-A of FIG. 3;

[19] **FIG. 15** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 15000;

[20] **FIG. 16** is a perspective view of an exemplary embodiment an auto-injector 16000;

[21] **FIG. 17** is a cross-sectional view taken along lines A-A of FIG. 3 of an exemplary embodiment of a system 17000;

[22] **FIG. 18A** is an end view of an exemplary embodiment of a system 18000;

[23] **FIG. 18B** is a cross-sectional view taken along lines A-A of FIG. 18A of an exemplary embodiment of a system 18000;

[24] **FIG. 19** is a cross-sectional view taken along lines A-A of FIG. 18A of an exemplary embodiment of a system 19000;

[25] **FIG. 20** is a cross-sectional view taken along lines A-A of FIG. 18A of an exemplary embodiment of a system 20000;

[26] **FIG. 21A** is a cross-sectional view taken along lines A-A of FIG. 18A of an exemplary embodiment of a system 21000;

[27] **FIG. 21B** is a front view of an exemplary embodiment of a system 21000;

[28] **FIG. 22A** is a cross-sectional view taken along lines A-A of FIG. 18A of an exemplary embodiment of a system 22000;

[29] **FIG. 22B** is a front view of an exemplary embodiment of a system 22500;

[30] **FIG. 23** is a perspective view of an exemplary embodiment an auto-injector 23000;

[31] **FIG. 23** is a cross-sectional view taken along lines A-A of FIG. 18A of an exemplary embodiment of a system 23000;

[32] **FIG. 24** is a perspective view of an exemplary embodiment an auto-injector 24000;

[33] **FIG. 25** is a perspective view of an exemplary embodiment an auto-injector 25000; and

[34] **FIG. 26** is a block diagram of an exemplary embodiment an information device 26000.

Definitions

[35] When the following terms are used substantively herein, the accompanying definitions apply:

[36] **a** – at least one.

[37] **activate** – to actuate and/or set in motion and/or action.

[38] **activity** – an action, act, step, and/or process or portion thereof.

[39] **actuating portion** – that part that puts something into action.

[40] **actuation lock** – a device adapted to prevent actuation, such as, for example a pivotable, translatable, keyed, squeezable, and/or removable lock.

[41] **actuator** – a mechanism that puts something into action.

[42] **adapted to** – suitable or fit for a particular purpose.

[43] **and/or** – either in conjunction with or in alternative to.

[44] **apparatus** – a mechanism and/or device.

[45] **arm** – an elongated structural member, which need not be solely linear.

[46] **auto-injector** – device that allows a user to deliver a medicament without having to manually prepare the injection. Exemplary devices include pen delivered injectors, syringes, needleless injectors, gas powered auto-injectors, and/or any other auto-injector and/or medical device used to inject a medicament into a user/patient, etc.

[47] **automatically** – acting or operating in a manner essentially independent of external influence or control. For example, an automatic light switch can turn on upon "seeing" a person in its view, without the person manually operating the light switch.

[48] **axis** – a straight line about which a body or geometric object rotates or may be conceived to rotate.

[49] **can** – is capable of, in at least some embodiments.

[50] **channel** – a conduit for one or more fluids.

[51] **compressed gas** – a substantially pressurized substance, such as helium, nitrogen, and/or carbon dioxide, etc., in a gaseous form.

[52] **comprising** – including but not limited to.

[53] **contain** – to hold within.

[54] **contents** – a contained compressed gas.

[55] **credit card** – a card (usually plastic) that assures a seller that the person using it has a satisfactory credit rating and that the issuer will see to it that the seller receives payment for the merchandise and/or services delivered. Typically measuring in size from approximately 3 to approximately 4 inches in length, such as approximately 3.40 inches, 3.375 inches, 85 millimeters, etc., and from approximately 1.75 to approximately 2.75 inches in width, such as approximately 2.10 inches, 2.2125 inches, 2.5 inches, 55 millimeters, etc.

[56] **data** – distinct pieces of information, usually formatted in a special or predetermined way and/or organized to express concepts.

[57] **define** – to establish the outline, form, or structure of.

[58] **device** – a machine, manufacture, and/or collection thereof.

[59] **discharge** – to release from confinement; to emit.

[60] **driving force** – a force sufficient to cause, directly or indirectly, expulsion of an injectable medicament from one or more vials and/or from an auto-injector.

[61] **dry substance** – a material that is substantially free from liquid or moisture.

[62] **eject** – to expel.

[63] **embedded system** – a programmed hardware device comprising a microprocessor controlled by an operating system and/or control logic that is specifically designed for a particular kind of application. The operating system and/or control logic of an embedded system comprises a limited set of pre-defined functions that can not be modified or added to by additional user-installed software, although some embedded systems allow a user to modify values of variables and/or parameters of the pre-defined functions. Exemplary devices

that can comprise embedded systems are: medical devices, calculators, automobiles, airplanes, vending machines, toys, programmable logic controllers, appliances, refrigerators, microwave ovens, clothes washers, thermostats, alarm systems, sprinkler systems, lighting controllers, electronic equipment, laser printers, CD players, DVD players, watches, and/or digital cameras, etc.

[64] **escape port** – an opening for the exit of a gas.

[65] **expulsion** – the act of forcibly ejecting a fluid via a designed outlet of a container.

[66] **expulsion pressure** – a force applied over an area of a liquid, the force sufficient to expel the liquid in a predetermined manner.

[67] **extend** – to move out and/or away from.

[68] **extendable** – able to move out and/or away from.

[69] **fluid** – a gas and/or liquid.

[70] **fluidly coupleable** – able to be related via a fluid.

[71] **force initiator** – a source, such as a compressed gas container, spring, and/or chemical reaction, etc., capable of supplying a driving force.

[72] **frangible** – a device that is capable of being broken and/or penetrated to allow fluid to flow therethrough.

[73] **haptic** – involving the human sense of kinesthetic movement and/or the human sense of touch. Among the many potential haptic experiences are numerous sensations, body-positional differences in sensations, and time-based changes in sensations that are perceived at least partially in non-visual, non-audible, and non-olfactory manners, including the experiences of tactile touch (being touched), active touch, grasping, pressure, friction, traction, slip, stretch, force, torque, impact, puncture, vibration, motion, acceleration, jerk, pulse, orientation, limb position, gravity, texture, gap, recess, viscosity, pain, itch, moisture, temperature, thermal conductivity, and thermal capacity.

[74] **hard real-time** – relating to computer systems that provide an absolute deterministic response to an event. Such a response is not based on average event time. Instead, in such computer systems, the deadlines are fixed and the system must guarantee a response within a fixed and

well-defined time. Systems operating in hard real-time typically interact at a low level with physical hardware via embedded systems, and can suffer a critical failure if time constraints are violated. A classic example of a hard real-time computing system is the anti-lock brakes on a car. The hard real-time constraint, or deadline, in this system is the time in which the brakes must be released to prevent the wheel from locking. Another example is a car engine control system, in which a delayed control signal might cause engine failure or damage. Other examples of hard real-time embedded systems include medical systems such as heart pacemakers and industrial process controllers.

[75] **hazardous condition** – a situation marked by risk, danger, and/or peril.

[76] **housing** – something that covers, encloses, protects, holds, and/or supports.

[77] **in reaction to** – responding indirectly and/or directly to.

[78] **indicate** – to show, mark, signify, denote, evidence, evince, manifest, declare, enunciate, specify, explain, exhibit, present, reveal, disclose, and/or display.

[79] **indicator** – a device and/or substance that indicates.

[80] **information device** – any device capable of processing information, such as any general purpose and/or special purpose computer, such as a personal computer, workstation, server, minicomputer, mainframe, supercomputer, computer terminal, laptop, wearable computer, and/or Personal Digital Assistant (PDA), mobile terminal, Bluetooth device, communicator, "smart" phone (such as a Treo-like device), messaging service (e.g., Blackberry) receiver, pager, facsimile, cellular telephone, a traditional telephone, telephonic device, a programmed microprocessor or microcontroller and/or peripheral integrated circuit elements, an ASIC or other integrated circuit, a hardware electronic logic circuit such as a discrete element circuit, and/or a programmable logic device such as a PLD, PLA, FPGA, or PAL, or the like, etc. In general any device on which resides a finite state machine capable of implementing at least a portion of a method, structure, and/or or

graphical user interface described herein may be used as an information device. An information device can comprise components such as one or more network interfaces, one or more processors, one or more memories containing instructions, and/or one or more input/output (I/O) devices, one or more user interfaces coupled to an I/O device, etc.

[81] **injectable medicament** – a medicine, medication, drug, pharmaceutical, prescriptive, agent, antidote, anti-venom, hormone, stimulant, vasodilator, anesthetic, and/or nutritional supplement that is substantially ready for injection.

[82] **input/output (I/O) device** - any sensory-oriented input and/or output device, such as an audio, visual, haptic, olfactory, and/or taste-oriented device, including, for example, a monitor, display, projector, overhead display, keyboard, keypad, mouse, trackball, joystick, gamepad, wheel, touchpad, touch panel, pointing device, microphone, speaker, video camera, camera, scanner, printer, haptic device, vibrator, tactile simulator, and/or tactile pad, potentially including a port to which an I/O device can be attached or connected.

[83] **liquid** – a body of matter that exhibits a characteristic readiness to flow, little or no tendency to disperse, and relatively high incompressibility.

[84] **longitudinal** – of or relating to longitude or length.

[85] **machine instructions** - directions adapted to cause a machine, such as an information device, to perform a particular operation or function.

[86] **machine readable medium** – a physical structure from which a machine can obtain data and/or information. Examples include a memory, punch cards, etc.

[87] **may** – is allowed to, in at least some embodiments.

[88] **memory device** – an apparatus capable of storing analog or digital information, such as instructions and/or data. Examples include a non-volatile memory, volatile memory, Random Access Memory, RAM, Read Only Memory, ROM, flash memory, magnetic media, a hard disk, a floppy disk, a magnetic tape, an optical media, an optical disk, a compact disk, a CD, a digital versatile disk, a DVD, and/or a raid

array, etc. The memory device can be coupled to a processor and/or can store instructions adapted to be executed by processor, such as according to an embodiment disclosed herein.

[89] **method** – a process, procedure, and/or collection of related activities for accomplishing something.

[90] **microprocessor** – an integrated circuit comprising a central processing unit.

[91] **mixable** – dissolvable, dispersible, and/or capable of being put into so that the dry substance is diffused and/or commingled in the liquid.

[92] **needle** – a hollow, slender, sharp-pointed instrument used for injection. Includes cannulas.

[93] **network** – a communicatively coupled plurality of nodes.

[94] **network interface** – any device, system, or subsystem capable of coupling an information device to a network. For example, a network interface can be a telephone, cellular phone, cellular modem, telephone data modem, fax modem, wireless transceiver, ethernet card, cable modem, digital subscriber line interface, bridge, hub, router, or other similar device.

[95] **non-co-axial** – not having co-linear axes.

[96] **output device** – an apparatus configured to visually, audibly, and/or haptically render information to a human. Examples include an audible output sub-system (e.g., speaker, horn, buzzer, and/or piezoelectric transducer, etc.), a visual output sub-system (e.g., flag, marker, light, liquid crystal display (LCD), light emitting diode (LED), optical fiber, organic polymer display, electric paper, screen, display, monitor, and/or tube, etc.), and a haptic output sub-system (e.g., buzzer, vibrator, bulging portion, tactile stimulator, cooler, and/or heater, etc.), etc.

[97] **patient** – a receiver of an injectable medicament, such as a human, mammal, animal, etc.

[98] **piston** – a sliding piece which either is moved by, or moves against, fluid pressure.

[99] **pivotable** – capable of pivoting.

[100] **plurality** – the state of being plural and/or more than one.

[101] **predetermined** – established in advance.

[102] **processor** - a device and/or set of machine-readable instructions for performing one or more predetermined tasks. A processor can comprise any one or a combination of hardware, firmware, and/or software. A processor can utilize mechanical, pneumatic, hydraulic, electrical, magnetic, optical, informational, chemical, and/or biological principles, signals, and/or inputs to perform the task(s). In certain embodiments, a processor can act upon information by manipulating, analyzing, modifying, converting, transmitting the information for use by an executable procedure and/or an information device, and/or routing the information to an output device. A processor can function as a central processing unit, local controller, remote controller, parallel controller, and/or distributed controller, etc. Unless stated otherwise, the processor can be a general-purpose device, such as a microcontroller and/or a microprocessor, such the Pentium IV series of microprocessor manufactured by the Intel Corporation of Santa Clara, California. In certain embodiments, the processor can be dedicated purpose device, such as an Application Specific Integrated Circuit (ASIC) or a Field Programmable Gate Array (FPGA) that has been designed to implement in its hardware and/or firmware at least a part of an embodiment disclosed herein.

[103] **programmable logic controller (PLC)** – a solid-state, microprocessor-based, hard real-time computing system that is used, via a network, to automatically monitor the status of field-connected sensor inputs, and automatically control communicatively-coupled devices of a controlled system (e.g., actuators, solenoids, relays, switches, motor starters, speed drives (e.g., variable frequency drives, silicon-controlled rectifiers, etc.), pilot lights, ignitors, speakers, tape drives, printers, monitors, displays, etc.) according to a user-created set of values and user-created logic and/or instructions stored in memory. The sensor inputs reflect measurements and/or status information related to the controlled system. A PLC provides any of: automated input/output control; switching; counting; arithmetic operations; complex data manipulation; logic; timing; sequencing;

communication; data file manipulation; report generation; control; relay control; motion control; process control; distributed control; and/or monitoring of processes, equipment, and/or other automation of the controlled system. Because of its precise and hard real-time timing and sequencing capabilities, a PLC is programmed using ladder logic or some form of structured programming language specified in IEC 61131-3, namely, FBD (Function Block Diagram), LD (Ladder Diagram), ST (Structured Text, Pascal type language), IL (Instruction List) and/or SFC (Sequential Function Chart). Because of its precise and real-time timing and sequencing capabilities, a PLC can replace up to thousands of relays and cam timers. PLC hardware often has good redundancy and fail-over capabilities. A PLC can use a Human-Machine Interface (HMI) for interacting with users for configuration, alarm reporting, and/or control.

[104] **puncturer** – a device adapted to penetrate using a substantially sharp and/or tapered point, tip, edge, or the like.

[105] **pusher** – a device adapted to convert fluid pressure to mechanical movement.

[106] **render** – make perceptible to a human, for example as data, commands, text, graphics, audio, video, animation, and/or hyperlinks, etc., such as via any visual, audio, and/or haptic means, such as via a display, monitor, electric paper, ocular implant, cochlear implant, speaker, etc.

[107] **repeatedly** – again and again; repetitively.

[108] **reservoir** – a receptacle or chamber for storing and/or directing movement of a fluid.

[109] **resist** – to avoid and/or remain firm against the actions, effects, and/or force of.

[110] **retract** – to pull inward.

[111] **safety tab** – a removable device configured to prevent actuation of an auto-injector when the safety tab is in one orientation, and allow actuation when in another orientation.

[112] **sensed variable** – a measured parameter.

[113] **set** – a related plurality.

[114] **sheath** – a protective cover.

[115] **shield** – a protective device or structure.

[116] **soft real-time** – relating to computer systems that take a best efforts approach and minimize latency from event to response as much as possible while keeping throughput up with external events overall. Such systems will not suffer a critical failure if time constraints are violated. For example, live audio-video systems are usually soft real-time; violation of time constraints can result in degraded quality, but the system can continue to operate. Another example is a network server, which is a system for which fast response is desired but for which there is no deadline. If the network server is highly loaded, its response time may slow with no failure in service. This is contrasted with the anti-lock braking system where a slow down in response would likely cause system failure, possibly even catastrophic failure.

[117] **spring** – an elastic device, such as a coil of wire, that regains its original shape after being compressed or extended.

[118] **status** – a state or condition.

[119] **store** – to place, hold, and/or retain data, typically in a memory.

[120] **substantially** – to a great extent or degree.

[121] **system** – a collection of mechanisms, devices, data, and/or instructions, the collection designed to perform one or more specific functions.

[122] **tip** – a terminal end.

[123] **transfer** – to convey from one place to another.

[124] **translatable** – capable of being transferred from one place to another and/or of being moved with respect to something else.

[125] **triggerable** – capable of being actuated.

[126] **use indication** – information regarding a use of an auto-injector, such as information regarding any of auto-injector selection; auto-injector maintenance; auto-injector expiration; auto-injector replacement; medicament expiration; medicament selection; medicament mixing; injection delay; safety guard removal; auto-injector positioning; auto-injector orientation; actuator location; injection hazard avoidance; auto-injector actuation; injection duration; injection status; injection

error; auto-injector removal; auto-injector reuse; auto-injector recycling; and auto-injector disposal, etc.

[127] **user input** – human-provided information.

[128] **user interface** – any device for rendering information to a user and/or requesting information from the user. A user interface includes at least one of textual, graphical, audio, video, animation, and/or haptic elements. A textual element can be provided, for example, by a printer, monitor, display, projector, etc. A graphical element can be provided, for example, via a monitor, display, projector, and/or visual indication device, such as a light, flag, beacon, etc. An audio element can be provided, for example, via a speaker, microphone, and/or other sound generating and/or receiving device. A video element or animation element can be provided, for example, via a monitor, display, projector, and/or other visual device. A haptic element can be provided, for example, via a very low frequency speaker, vibrator, tactile stimulator, tactile pad, simulator, keyboard, keypad, mouse, trackball, joystick, gamepad, wheel, touchpad, touch panel, pointing device, and/or other haptic device, etc. A user interface can include one or more textual elements such as, for example, one or more letters, number, symbols, etc. A user interface can include one or more graphical elements such as, for example, an image, photograph, drawing, icon, window, title bar, panel, sheet, tab, drawer, matrix, table, form, calendar, outline view, frame, dialog box, static text, text box, list, pick list, pop-up list, pull-down list, menu, tool bar, dock, check box, radio button, hyperlink, browser, button, control, palette, preview panel, color wheel, dial, slider, scroll bar, cursor, status bar, stepper, and/or progress indicator, etc. A textual and/or graphical element can be used for selecting, programming, adjusting, changing, specifying, etc. an appearance, background color, background style, border style, border thickness, foreground color, font, font style, font size, alignment, line spacing, indent, maximum data length, validation, query, cursor type, pointer type, autosizing, position, and/or dimension, etc. A user interface can include one or more audio elements such as, for example, a volume control, pitch control, speed

control, voice selector, and/or one or more elements for controlling audio play, speed, pause, fast forward, reverse, etc. A user interface can include one or more video elements such as, for example, elements controlling video play, speed, pause, fast forward, reverse, zoom-in, zoom-out, rotate, and/or tilt, etc. A user interface can include one or more animation elements such as, for example, elements controlling animation play, pause, fast forward, reverse, zoom-in, zoom-out, rotate, tilt, color, intensity, speed, frequency, appearance, etc. A user interface can include one or more haptic elements such as, for example, elements utilizing tactile stimulus, force, pressure, vibration, motion, displacement, temperature, etc.

[129] **valve** – a device that regulates flow through a pipe and/or through an aperture by opening, closing, and/or obstructing a port and/or passageway.

[130] **vent** – to release from confinement.

[131] **via** – by way of and/or utilizing.

[132] **vial** – a closable vessel.

Detailed Description

[133] Exposure, such as via ingestion, inhalation, and/or injection, to certain allergens, toxins, and/or other substances can cause profound reactions for some and/or all people and/or animals. For example, certain people are highly allergic to certain substances, such as peanuts, shellfish, particular drugs, certain proteins, bee venom, insect bites, etc. The allergic response to the exposure can lead to anaphylactic shock, which can cause a sharp drop in blood pressure, hives, and/or substantial breathing difficulties caused by severe airway constriction. As another example, inhalation of certain nerve agents can cause severe physiological trauma.Responding rapidly to such exposures can prevent injury and/or death. For example, in response to an exposure leading to anaphylactic shock, an injection of epinephrine (i.e., adrenaline) can provide substantial and/or complete relief from the reaction. As another example, injection of an antidote to a nerve agent can greatly reduce and/or eliminate the potential harm of the exposure. As yet another example, rapid injection of certain drugs, such as a beta blocker, blood

thinner, nitroglycerine, antihistamines, insulin, and opioids, etc., can provide substantial relief from various dangerous medical conditions.

[135] Thus, certain exemplary embodiments provide systems, devices, and/or methods for rapidly injecting a medicament.

[136] Certain exemplary embodiments comprise an apparatus, comprising: a compressed gas container; a plurality of vials adapted to store a liquid medicament, each vial defining a longitudinal axis, the longitudinal axes of the plurality of vials parallel and non-co-axial, the plurality of vials fluidly coupleable to an actuating portion of a contents of the gas container; and a plurality of pistons, each piston adapted to move within a corresponding vial from the plurality of vials, the plurality of pistons adapted to, in response to discharge of the actuating portion of the contents of the compressed gas container, transfer at least a portion of the liquid medicament from the plurality of vials and through a needle that is extendable into a patient. Certain exemplary embodiments comprise a method comprising a plurality of activities, comprising: discharging an actuating portion of a contents of a compressed gas container, the compressed gas container contained within an apparatus; in reaction to said discharging activity, moving a piston within a vial, the vial one of a plurality of vials contained within the apparatus, each vial adapted to store a liquid medicament, each vial defining a longitudinal axis, the longitudinal axes of the plurality of vials parallel and non-co-axial, the plurality of vials fluidly coupleable to a contents of the gas container; and transferring a liquid medicament from the vial and through a needle that is extendable into a patient.

[138] **FIG. 1** is a perspective view, **FIG. 2** is a front view, and **FIG. 3** is a side view, of an exemplary embodiment of a system 1000, which can comprise a housing 1100, which, in certain operative embodiments, can comprise a handheld portion 1800 separated via an actuation guard 1200 from an actuation bar 1300. Actuation guard 1200 can prevent accident activation of system 1000. Housing 1100 can be constructed of a durable material, such as stainless steel, aluminum, polycarbonate, etc., to protect a compressed gas container, medicament, injection apparatus and/or user of system 1000. The injection apparatus can be actuated by a fluid pressure, such as pressure provided by the

compressed gas, which upon completion of its actuation duties can escape housing 1100 via gas escape opening, such as via status indicator 1400.

[139] A status of a system 1000 can be determined via status indicator 1400, which can provide a view, such as via a UV blocking, photo-sensitive, and/or translucent window, into an interior of housing 1100. Viewable through the window can be a status of medicament carried by housing 1100, a location of a needle and/or injection apparatus for the medicament, and/or an activation status of system 1000. For example, if the medicament has aged to the point of discoloration, which aging might or might not render the medication useless, harmful, etc., status indicator 1400 can allow that situation to be determined. In certain exemplary embodiments, gas can escape housing 1100 via status indicator 1400 and/or another opening in housing 1100.

[140] Certain exemplary embodiments of system 1000 can provide a compact medicament delivery mechanism that can efficiently and/or rapidly deliver a prescribed dose. The length (L) and width (W) of system 1000 can be similar to that of a credit card, and the thickness (T) can be less than one inch. Thus, certain exemplary embodiments of system 1000 can provide a conveniently carried, easy-to-use, easy to activate drug delivery apparatus that can require little to no training to safely carry, use, and/or dispose of.

[141] To assist a user in positioning system 1000 in a correct orientation for injection, system 1000 and/or housing 1100 can provide various tactile clues. For example, a top 1110 of housing 1100 can be rounded, and a bottom 1120 of actuation bar 1300 of housing 1100 can be flat. Other tactile clues are also possible, such as bulges, ribs, grooves, gaps, roughened surfaces, indentations, etc.

[142] **FIG. 4** is a cross-sectional view taken along lines A-A of **FIG. 3** of an exemplary embodiment of a system 1000 in a first operative position. **FIGs. 5, 6, 7, 8, and 9** show system 1000 of **FIG. 4** in second, third, fourth, fifth, and sixth operative positions, respectively.

[143] System 1000 can comprise a housing 1100, handheld portion 1800, actuation guard 1200, and/or actuation bar 1300. System 1000 can comprise system actuator 2000, gas reservoirs 3000, medicament actuator 4000, medicament storage assembly 5000, medicament carrier 9000, needle assembly 6000, use indicator 7000, and/or gas vent mechanism 8000, etc.

[144] Upon removal, release, rotation, and/or relocation of actuation guard 1200, system actuator 2000 can be adapted to rapidly discharge an actuating portion of a contents of a compress gas container. For example, system actuator 2000 can comprise a compressed gas container 2400, which initially can contain a compressed gas 2500, an actuating portion of which can be released from container 2400 by penetration of a gas port 2600 via a point of a puncturer 2700. Upon removal and/or relocation of actuation guard 1200, actuation bar 1300 can be moved closer to and/or in contact with handheld portion 1800. Upon removal and/or relocation of actuation guard 1200, gas container 2400 can be brought into contact with puncturer 2700 via extension of a pre-compressed spring 2300 and/or movement of a actuation stick 2200. Thus, actuation guard 1200 can prevent accident activation of system 1000 and/or unintended discharge of an actuating portion of the contents 2500 of gas container 2400.

[145] Once gas port 2600 has been punctured, an actuating portion of compressed gas 2500 can escape from container 2400 and flow via gas reservoirs 3000, such as gas channel 3100. The flowing gas can meet and/or apply gas pressure to medicament actuator 4000, which can comprise a pusher 4100, which can travel within a sleeve 1500 defined by walls 1520. Sleeve 1500 can be constructed of metal, stainless steel, aluminum, plastic, polycarbonate, etc. Seals 4200, such as o-rings, can resist gas leakage, such as past pusher 4100 and/or out of housing 1100. Thus, pusher 4100 can function as a piston traveling within a cylinder, although it is not necessarily required that the cross-sectional shape of sleeve 1500 be round.

[146] Medicament actuator 4000 can interface with medicament storage assembly 5000. For example, medicament actuator 4000 can comprise a plurality of

plungers 4300, each of which can be capped with a piston 4400 which can sealingly slide and/or move within a corresponding vial 5100 containing a liquid medicament 5200. For example, in response to pressure applied by an actuating portion of the contents 2500 of compressed gas container 2400, pusher 4100 can cause plungers 4300 and/or pistons 4400 to simultaneously move. The number of corresponding sets of plungers 4300, pistons 4400, and/or vials 5100 can be 2, 3, 4, 5, 6, or more. Pistons 4400 can be constructed of a resilient, durable, and/or sealing material, such as a rubber. Each plunger 4300 from the plurality of plungers can define a longitudinal axis, the longitudinal axes (e.g., axes 4310, 4320, 4330, 4340) of the plurality of plungers parallel, non-coaxial, and/or co-planar.

[147] Each vial 5100 from the plurality of vials can be substantially cylindrical with a substantially round and/or substantially elliptical cross-sectional shape. Thus, each vial 5100 can define a longitudinal axis, the longitudinal axes of the plurality of vials parallel, non-coaxial, and/or co-planar. The longitudinal axis of each vial can be co-axial with the longitudinal axis of its corresponding plunger.

[148] Each vial can be capped at one end with a frangible 5300, which can be burst when piston 4400 generates sufficient pressure upon medicament 5200, thereby allowing at least a portion of medicament 5200 to flow out of vial 5100 and into medicament carrier 9000. Thus, the plurality of vials can be fluidly coupleable to the actuating portion of the contents 2500 of gas container 2400.

[149] Medicament carrier 9000 can hold each of vials 5100 and can travel within sleeve 1500. Medicament carrier 9000 can comprise a plurality of channels 9200 adapted to receive medicament 5200 as it exits its respective vial 5100, and direct medicament 5200 to a common conduit 9300. Medicament carrier 9000 can interface with needle assembly 6000 and/or use indicator 7000.

[150] From common conduit 9300, medicament 5200 can enter needle assembly 6000, such as into a single needle 6100 via which medicament can approach

needle tip 6200. As medicament actuator 4000 and/or medicament carrier 9000 are driven toward actuator bar 1300, needle tip 6200 can penetrate an end 6400 of needle sheath 6300 and exit actuator bar 1300 at needle port 1340.

[151] Referring to **FIG. 5**, upon movement of actuation bar 1300 closer to handheld portion 1800, sheath seat 1330 can come in contact with sheath tip 6400, thereby causing sheath 6300 to buckle and/or crumble. As actuator bar 1300 comes in contact with handheld portion 1800, bar stop 1320 can approach medicament carrier stop 9400, while carrier spring 1600 is compressed.

[152] Referring to **FIG. 6**, as at least a portion of contents 2500 of gas container 2400 escapes, it can flow through channel 3100. The gas, which can still be relatively pressurized, can begin to accumulate behind pusher 4100 to form an expanding gas chamber 3200 and to cause medicament actuator 4000, medicament storage assembly 5000, and medicament carrier 9000 to slide together within sleeve 1500. As medicament actuator 4000, medicament storage assembly 5000, and medicament carrier 9000 slide closer to actuator bar 1300, spring 1600 becomes increasingly compressed between bar stop 1320 and medicament carrier stop 9400. As medicament actuator 4000, medicament storage assembly 5000, and medicament carrier 9000 slide closer to actuator bar 1300, needle tip 6200 can extend further from actuator bar 1300 and sheath 6300 can become further compressed and/or deformed. At its ultimate extension point, needle tip 6200 can extend from housing 1100 from approximately 0.25 millimeters to approximately 20 millimeters, including all values and subranges therebetween, such as up to approximately 2 millimeters, greater than approximately 5 millimeters, from approximately 5.13 millimeters to approximately 9.98 millimeters, etc.

[153] Referring to **FIG. 7**, as gas chamber 3200 continues to expand, medicament carrier 9000 can be driven until medicament carrier stop 9400 contacts actuator bar stop 1300 thereby resisting further travel of medicament carrier 9000. At that point, additional expansion of gas chamber 3200 can cause medicament actuator 4000, pusher bar 4100, plungers 4300, and/or pistons 4400 to initiate travel with respect to medicament storage assembly 5000,

thereby generating an expulsion pressure in vials 5100, and/or thereby rupturing frangibles 5300 and allowing medicament 5200 to enter medicament carrier 9000, and begin flowing through medicament channels 9200, medicament conduit 9300, needle 6100, and/or out needle tip 6200 and into a patient. Alternatively, frangibles 5300 can be replaced and/or augmented by a frangible located at or near where medicament conduit 9300 couples to needle 6100. Frangibles 5300 can be constructed of a thin, taught, resilient, durable, and/or sealing material potentially having a predetermined yield strength, such as a rubber, such as chromo butyl rubber, and/or of a relatively brittle material potentially having a predetermined yield strength, such as ceramic, certain plastics, such as polystyrene, etc.

[154] As medicament carrier stop 9400 contacts actuator bar stop 1300, medicament carrier hooks 9600 can engage with engagement receivers 7100 in use indicator 7000.

[155] Referring to **FIG. 8**, as gas chamber 3200 continues to expand, medicament actuator 4000, pusher bar 4100, plungers 4300, and/or pistons 4400 can continue moving until they complete their travel within medicament storage assembly 5000, thereby expelling a predetermined dose of medicament 5200 from vials 5100, out of needle assembly 6000, external to housing 1100, and/or into the patient. As gas chamber 3200 reaches its maximum size, medicament actuator 4000, pusher bar 4100, plungers 4300, and/or pistons 4400 can continue moving until they complete their travel with respect to medicament carrier 9000, thereby causing gas release actuator 9700 to engage with gas release valve 8200. Engagement of gas release actuator 9700 with gas release valve 8200 can cause within gas chamber 3200 to exit gas chamber 3200, discharge away from pistons 4400, and/or exhaust from system 1000 and/or housing 1100, such as via status indicator 1400 and/or a gas escape port located on housing 1100).

[156] Referring to **FIG. 8** and **FIG. 9**, as sufficient gas is vented from gas chamber 3200, the pressure applied by the gas in gas chamber 3200 can decrease until the force applied by the gas on medicament actuator 4000 is less than the force

of compressed spring 1600. Thus, spring(s) 1600 can begin to expand, thereby moving medicament carrier 9000, vial assembly 5000, and medicament actuator 4000 away from actuator bar 1300 and helping to exhaust gas from gas chamber 3200. As medicament carrier 9000 moves, use indicator 7000 can travel with it, due to the engaged relationship of medicament carrier hooks 9600 and engagement receivers 7100 and/or engagement catches 7200 in use indicator 7000. As use indicator 7000 moves away from actuation bar 1300, sheath 6300 can travel with it, thereby creating a gap between sheath tip 6400 and needle port 1340, and thereby exposing a previously non-visible colored portion 1350 of actuation bar 1300 and/or providing an indication that system 1000 has been used (and likely substantially exhausted of its medicament), thereby discouraging any further attempts to use system 1000.

[157] As medicament carrier 9000 moves away from actuator bar 1300, needle 6100 can retract into sheath 6300 which un-buckles and/or un-deforms towards its original shape. Eventually, needle 6100 can retract completely within the boundaries of housing 1100, thereby tending to prevent accidental needle sticks after the initial injection and/or potentially reducing and/or eliminating a sharps hazard.

[158] In certain exemplary embodiments, system actuator 2000 can comprise a finger triggered, twistable, pivotable, and/or lever-operated mechanism. For example, system actuator 2000 can comprise a twistable handle that can screw into gas port 2600. In certain exemplary embodiments, system actuator 2000 can be a finger trigger located on a side of the housing.

[159] **FIG. 10** is a flowchart of an exemplary embodiment of a method 10000 for operating a medicament delivery apparatus. At activity 10100, an actuation lock for the apparatus is released. At activity 10200, an actuating portion of the contents of a compressed gas container are released. At activity 10300, via pressure provided by the released gas, a needle is extended from the apparatus. At activity 10400, via pressure provided by the released gas, a piston applies pressure to a medicament stored in one of a plurality of vials. At activity

10500, a frangible containing the medicament in the vial is burst. At activity 10600, the medicament flows from the vial, through the needle, and into a patient. At activity 10700, once a predetermined dose is expelled and/or injected, the needle is withdrawn from the patient and/or retracted into the pre-use bounds of the apparatus. At activity 10800, the apparatus is rendered unusable for additional injections and/or indicated as previously utilized.

[160] **FIG. 11** is a perspective view of an exemplary embodiment of system 1000, showing actuation guard 1200 removed from housing 1100, so that actuation guard 1200 no longer separates actuator bar 1300 from handheld portion 1800. Actuation guard 1200 can comprise a grippable portion 1220 that can be gripped by a user to pull actuation guard 1200 away from housing 1100, thereby allowing system 1000 to be activated, such as via slapping actuator bar 1300 against a thigh of the user. Actuation guard 1200 can comprise an actuation stick separator portion 1240, that can keep separate actuation stick prongs 2240 when actuation guard 1200 is installed on housing 1100. Actuation guard 1200 can comprise a guard portion 1260 that can separate actuator bar 1300 from handheld portion 1800 when system 1000 is not in use and/or when system 1000 has not been used.

[161] **FIG. 12** is a perspective cross-sectional view taken along lines B-B of **FIG. 11**, and **FIG. 13** is a perspective view of an exemplary embodiment of actuation stick 2200. Referring to **FIGs. 12** and **13**, system 1000 can comprise housing 1100, actuation bar 1300, and system actuator 2000, which can comprise prong squeezer 1390, actuation stick 2200, prong retainer 2100, spring 2300, upper spring retainer 2260, gas container 2400, gas port 2600, and/or puncturer 2700. When actuation bar 1300 is pressed firmly against a user's body, such as via slapping housing actuation bar against the user's thigh, buttocks, and/or arm, prong squeezer 1390 can urge prong tips 2220 of prongs 2240 of actuation stick 2200 toward one another. Note that prong tips 2200 can have a triangular, wedge, angular, and/or frustro-conical shape. As prongs tips 2220 slide along the angled V-groove of prong squeezer 1390, prong catches 2230 can substantially loose contact with prong retainer 2100. This can allow compressed spring 2300 to rapidly urge actuation stick 2200

and gas container 2400 toward puncturer 2700, which can penetrate gas port 2600, thereby allowing gas to escape from gas container 2400. Although any of many different types of gas containers can be utilized, an exemplary gas container can be obtained from Leland Limited, Inc. of South Plainfield, NJ.

[162] **FIG. 14** is a cross-sectional view of an exemplary embodiment of gas venting mechanism 8000 of system 1000 taken along lines **A-A** of **FIG. 3**. System 1000 can comprise handheld portion 1800, actuator bar 1300, sleeve 1500. As pistons 4440 near the limit of their travels, medicament 5200 can be expelled along medicament path 5900, which can extend past frangible 5300, through medicament channels 9200, medicament conduit 9300, and needle 6100, and into the body of a user, such as subcutaneously, intramuscularly, and/or at a depth of from approximately 0.25 millimeters to approximately 20 millimeters, including all values and subranges therebetween, such as up to 2 millimeters, greater than 5 millimeters, etc.

[163] As pistons 4440 near the limit of their travels, engagement of gas release actuator 9700 with gas release valve 8200 can cause compressed spring 8300 to move valve arm such that o-ring 8400 is urged away from its seat 8500. This movement can reveal a passage 8600, via which gas can exit gas chamber 3200 along gas exhaust path 8900, which can extend between sleeve inner walls 1520 and outer walls 9100 of medicament carrier 9000. Eventually, gas exhaust path 8900 can extend between handheld portion 1800 and actuator bar 1300. Likewise, an alternative embodiment of valve 8200, made of rubber or any other resilient material, can be placed across seat 8500 to provide a seal that, once gas release actuator 9700 interacts with valve 8200, allows valve 8200 to bend or flap upwards away from seat 8500, causing the gas to escape via passage 8600.

[164] The following paragraphs expands on the above and describe various exemplary embodiments relating to compact auto-injectors that can comprise and/or utilize a vial or a plurality of vials to store and/or contain an injectable medicament. These auto-injectors can have a compact form factor, such as approximately the size of a credit card. There are many methods of delivering

such medicaments in such compact devices. The below descriptions cover multiple methods and/or mechanisms that can effectively administer a medicament using a compact auto-injector.

Exemplary Embodiment One: ***Methods of Utilizing an Auto-injector***

[165] This exemplary embodiment describes a method of implementing an auto-injector utilizing a spring and/or gas driven system to administer a medicament and/or comprises a needle protection system.

[166] An embodiment for delivering medicament from a chamber can comprise a vial or plurality of vials; said chamber in communication with a needle that can be concealed initially by some shield and/or sheath; extending said needle from the sheath at least 1mm and/or inserting the needle past a needle insertion point to an injection site at a depth of at least 5mm; the application of a force that can originate from the contents of a gas cylinder and/or by means of a spring or multiple springs sufficient to eject medicament held within said chamber into the needle and/or through the needle insertion point to a depth of at least 5mm to deliver up to 5 ml of medicament into the injection site in less than 5 seconds; wherein the medicament can be injected and/or held through the use of a vial system that comprises a plunger, vial(s), reservoir, and/or needle that can be located within said chamber; wherein the force can be applied on the plunger at the proximal end allowing for the plunger, vial(s), reservoir, and/or needle to travel towards the distal end of the housing; wherein the plunger can slideably travel through the vial towards the distal end to allow for the appropriate dose of medicament to be delivered; wherein the needle insertion point can be located more superficial than the injection site; wherein the needle can have a length of at least 6mm and/or the medicament can be ejected at a pressure of at least 25 p.s.i. at a rate of at least 0.20 ml/sec; and/or wherein the needle can retract into the shield and/or housing and/or a needle protection portion slides over the needle following delivery of the medicament.

[1] **FIG. 15** shows an exemplary embodiment an auto-injector 15000. Though the figure shows the force mechanism used as being compressed gas, the force

method can be created by a spring force (See description of **FIG. 18** below). The top of the housing can be laser-welded to ensure stability due to high pressure. Likewise, the entire housing may be made smaller by eliminating screws and/or pins holding the base and/or top to the housing. In **FIG. 15**, this can be completed by adding hooks to the base. The hooks can allow the base to slide into the housing, thus pushing the detents inward and allowing for the puncturing of the gas cylinder by the compressed spring. These hooks can also click into the housing, making the base unable to move post-injection; this eliminates re-use of the device and acts as an indicator to determine if the device has been used or if the device has not been activated. The gas release mechanism is also a novel addition to the device. A rubber flap and/or other resilient material can be located inside the plunger bar. A solid piece or member can stick up from the reservoir near the top of the vials. Once the plunger bar dispenses the medicament, this piece can push the rubber flap up, thereby releasing excess gas in the system. The puncturing device for the gas cylinder could be a roll-pin that is sliced at a 45 degree angle to ensure sharpness for puncturing.

[167] **FIG. 16** shows the safety tab used to protect the user from accidental activation. **FIG. 16** also shows an extended portion of the safety tab with grooves added to it. This can aid the user in removing the safety tab by creating a larger gripping surface and/or a more tactile feel to the tab.

Exemplary Embodiment Two: *Chemical Reaction*

[168] This exemplary embodiment involves an auto-injection system that utilizes a chemical reaction as an activation mechanism to deliver the medicament into a patient. It also comprises a needle protection system.

[169] This exemplary embodiment comprises a delivery system that can encompass a housing, vial or plurality of vials, plunger for each vial, single needle or needle cannula, and medicament or medicaments within the vial or plurality of vials; the vial or plurality of vials in communication with the plunger(s) at proximal end and in communication with a reservoir that contains a single needle or needle cannula at the distal end; the needle can be protected by some

sheath/ shield; a chemical reaction capable of occurring when one chemical is allowed to interact with another chemical and/or a substance that may create such a reaction through the use of some activation mechanism; and said chemical reaction that can generate a force that is strong enough to drive said plunger, vial, reservoir, and needle towards the distal end of the housing; the needle exiting said sheath/shield and entering an injection site; the plunger(s) slideable in the vial(s) that contain the medicament; and said medicament exiting the vials into through the reservoir and needle cannula into the injection site; upon exit of the desired contents of the vial, the entire needle, reservoir, vial, and plunger assembly can retract towards the proximal end of housing by some means such as a wire, spring, o-ring, and/or rubber membrane and/or a needle protection portion slides over the needle following delivery of the medicament.

[170] **FIG. 17** is a view of the compact injector with several modifications to allow for a chemical reaction to occur as the primary force method in order to deliver the medication. In the particular drawing, the puncturing pin can include a rough surface. Likewise, the container used in the device can have a similar rough material and/or surface and can contain mostly Sodium Azide (NaN3). Once the spring (attached to the container) is activated, the two rough surfaces can simultaneously come in contact with each other to create a spark and puncture the Azide container. This can create an immediate chemical reaction because of the spark. The reaction (2 NaN3 —> 2 Na + 3 N2) can form hot nitrogen gas and sodium in order to create enough force to inject the medication. A modification to this figure can be made to include another container at the top in place of the puncturing pin that can break open from the force of the spring and second container, thus mixing the two chemicalss and can cause a chemical reaction to occur in order to produce the force needed.

Exemplary Embodiment Three: ***The Spring Driven Injector***

[171] Certain exemplary embodiments of the auto-injector can use a spring or multiple springs to inject the medicament into a patient. The novelty of this system can lie in the orientation of the activation springs and the vial system

(that comprises the plunger, vial(s), reservoir and the needle/cannula) system. Because the activation springs can be located in parallel to the vial system, the device can be smaller than existing devices on the market (that are linear in nature), potentially having a form factor that is approximately the size of a credit card.

[172] Certain exemplary embodiments can comprise a delivery system that can encompass a housing, vial or plurality of vials, plunger for each vial, single needle or needle cannula, and medicament and/or medicaments within the vial or plurality of vials; the vial or plurality of vials in communication with the plunger(s) at proximal end and in communication with a reservoir that contains a single needle or needle cannula at the distal end; the needle protected by some sheath/ shield; the housing further comprising at least one spring (this can comprise a gas spring, coil spring, leaf spring, etc.) wherein the spring(s) is parallel to the plunger, vial(s), and reservoir system and is in communication with a solid member (that can be made of rubber, plastic, metal, and/or some other resilient material) that is also in communication with the proximal end of the plunger such that when the spring(s) is activated, a force is applied on the plunger at the proximal end allowing for the plunger(s), vial(s), reservoir, and needle to travel towards the distal end of the housing; wherein the plunger can slideably travel through the vial towards the distal end to allow for the appropriate dose of medicament to be delivered; the solid member is displaced away from the plunger, which can allow for the retraction of the entire needle, reservoir, vial(s), and plunger assembly towards proximal end of housing by some means such as a wire, spring, o-ring, and/or rubber membrane and/or for a needle protection portion to slide over the needle following delivery of the medicament.

[173] **FIG. 18** shows several views of the spring driven injector. The primary force used to push down the pusher bar, vial system, reservoir, and needle can be provided by compressed springs. In the cross-section drawing, two springs can be located on the outside of the central chamber (containing the pusher bar, vials, reservoir, and needle). The springs can be held in place by a rod coupled with hooks. Each spring can have a rolling solid member attached to

it that is also connected to a bar that is held into a notch/indentation in the reservoir near the bottom of the vials. Furthermore, a solid beam can wrap around the top of the pusher bar and can attach to the aforementioned bar. The bar can slide in and out of the reservoir and the solid beam, but only if the rolling solid member is rolled *away* from the reservoir and beam. The device can be activated by the user pulling out the safety mechanism and pushing downward on the outside sleeve. This can cause the hooks from the rods holding the springs in place to pinch inward, thereby releasing the springs forcefully downward. As the springs are driven downward, the rolling solid member and bar can roll down through the solid member passage. As the rolling solid member is moved, the solid beam wrapped around the pusher bar can come down as well, pushing the needle into the user. The medication can then be delivered into the user and/or patient once the rolling solid member goes down even further, which can be continually driven by the force of the springs. The solid member passage eventually can turn away from the vial system and reservoir (also shown in the side view drawing as a hidden line). This can slide the bar out of the reservoir and out of the beam, allowing for the retracting springs to push the pusher bar, vials, reservoir, and needle back into the housing.

Exemplary Embodiment Four: *Pulley System*

[174] This exemplary embodiment can utilize a pulley system as the activation mechanism for injecting medicament into the patient and that can also comprise a needle protection system.

[175] Certain exemplary embodiments can comprise a delivery system that can encompass a housing, vial or plurality of vials, plunger for each vial, single needle or needle cannula, and medicament or medicaments within the vial or plurality of vials; the vial or plurality of vials in communication with the plunger(s) at proximal end and in communication with a reservoir that can contain a single needle or needle cannula at the distal end; the needle that can be protected by some sheath/ shield; the housing further comprising one or more spring pulley system(s) that can constitute a spring connected to some slideable resilient material such as a string, wire, wire coil, flat metallic band,

etc. at the proximal end of the housing, and said material that can travel through a channel in the housing from the proximal end of the housing towards the distal end of the housing and then returning through a parallel channel towards the proximal end wherein this material is connected to a solid member (made of rubber, plastic, metal, and/or some other resilient material); the solid member in communication with the proximal end of the plunger such that when the spring is activated the spring can produce enough force to allow the pulley system to operate by having the resilient material, such as a cord, which can forcefully travel towards the proximal end of the housing and can cause the cord to move the solid member in communication with the plunger, vial(s), reservoir, and/or needle towards the distal end; wherein the needle can exit said sheath/shield and can enter an injection site; the plunger(s) slideable in the vial(s) that can contain the medicament; and said medicament can exit the vials into through the reservoir and/or needle cannula into the injection site; upon exit of the desired contents of the vial, the solid member can be displaced away from the plunger allowing for the entire needle, reservoir, vial(s), and/or plunger assembly to retract towards the proximal end of housing by some means such as a wire, spring, o-ring, and/or rubber membrane and/or a needle protection portion to slide over the needle following delivery of the medicament.

[176] A pulley system is shown in **FIG. 19** as the primary method for forcing the pusher bar, vials, reservoir, and needle down for medicament injection. Similar to the above spring-driven injector, the activation springs can be located parallel to the vial system and the device can be activated by the user pushing down on the outside sleeve of the device. The use of a pulley system can create a mechanical advantage, producing the proper force needed to efficiently push down the vial system and deliver the proper dose of medication. **FIG. 19** shows a bar that can be connected to the end of the rod/spring member. This bar can be connected to the pulley system (that can comprise some resilient and/or moveable material). The other end of the pulley system can be connected on top of the pusher bar to a beam that can be able to slide when moved to a certain position. As the springs are driven downward, the pulley system can pull the pusher bar, vials, reservoir, and

needle down as well. Similar to the spring-driven injector, the solid beam member on top of the pusher bar can slide down the solid member passage and eventually dislodge from the pusher bar. Once this occurs, the entire system can retract back within the housing due to the force from the retracting springs.

Exemplary Embodiment Five: ***The Needleless Injector***

[177] This exemplary embodiment can comprise a Needleless Injector that can be gas and/or spring activated and that can allow for a user to inject a medicament into a patient without the use of a needle. The use of a plurality of vials can be considered the novel component and can allow the device to be compact in nature, such as having the approximate length and width similar to that of a credit card.

[178] Certain exemplary embodiments for delivering medicament from a chamber can comprise a plurality of vials; the said chamber in communication with a passage into a small injection opening; the application of a force that can originate from the contents of a gas cylinder and/or by means of at least one spring that can eject medicament held within said chamber into the passage to the small injection opening, which can be defined and/or created by the housing and/or a small sterile rod that can be a needle or cannula allowing for the slight puncturing of the injection site in order to allow the medicament to be delivered, and through the tip of this small injection opening to a depth of at least 1mm, that can deliver up to 5 ml of medicament into the injection site; wherein the medicament can be injected and held through the use of a vial system that comprises a plunger, vial(s), and/or reservoir all located within said chamber; wherein the force can be applied on the plunger at the proximal end allowing for the plunger, vial(s), and/or reservoir to travel towards the distal end of the housing; wherein the plunger can slideably travel through the vial towards the distal end to allow for the appropriate dose of medicament to be delivered through the reservoir into the small injection opening; wherein the injection opening point can be located more superficial than the injection site; wherein the medicament can be ejected at a pressure of at least 25 p.s.i.

(For example, in such embodiments, the pressure to deliver a dose of 0.5cc's could be about 100 pounds of force).

[179] **FIG. 20** depicts the components of the needleless injector. The injector can be activated by removing a safety tab and pushing down on the housing. The rod with hooks holding the spring in place can be initiated by the base moving upwards and pushing the hooks inward. The spring can drive the high pressure gas cylinder into a puncturing pin, releasing the gas cylinder contents. The gas cylinder contents can push down the pusher bar, vials, and reservoir into the small opening at the base of the device near the injection site. A tiny cannula and/or needle can be located at the bottom of the reservoir and/or can be used for slightly puncturing the injection site. This slight puncture can allow the medicament stored in the vial to flow through the reservoir and into the injection site. Once the pressure is released, the entire system (including the pusher bar, vials, and reservoir) can be pushed back up within the housing by the retracting springs.

Exemplary Embodiment Six: ***The Multi-Pharmaceutical Injector***

[180] This exemplary embodiment can comprise a compact auto-injector that can incorporate a plurality of vials, allowing for multiple medicaments to be injected at one time or at different times. The use of a plurality of vials can be considered the novel component and also can have the advantage of creating a device that is compact in nature, such as one having the length and width of a credit card. The device also can comprise a needle protection system.

[181] Certain exemplary embodiments for delivering medicament from a chamber can comprise a plurality of vials; the said chamber or chambers in communication with a needle or needles that can be concealed initially by shields and/or sheaths; that can extend said needle from the said sheath at least 1mm and can insert the needle past a needle insertion point to an injection site at a depth of at least 5mm; the application of a force and/or forces that can originate from the contents of a gas cylinder and/or multiple gas cylinders, and/or by means of a spring and/or springs sufficient to eject medicament held within said chamber into the needle and through the needle insertion point;

wherein the medicament can be injected and held through the use of a vial system and/or vial systems that can comprise a plunger, vial, reservoir, and/or needle all located within said chamber(s); wherein the force can be applied on the plunger at the proximal end allowing for the plunger, vial, reservoir, and/or needle to travel towards the distal end of the housing; wherein the plunger can slideably travel through the vial towards the distal end to allow for the appropriate dose of medicament to be delivered; wherein the needle insertion point can be located more superficial than the injection site. The device potentially having a multitude of said components (including but not limited to vials, plungers, gas cylinders, springs, needles, reservoirs, sheaths, shields, chambers, and/or retracting springs) in order to administer multiple medicaments into a patient at one time and/or at different times, as one dose and/or in multiple doses, depending on when each individual system is activated. The device can have selectors and/or other mechanisms to allow the user to choose which medicament to administer. Each individual system can comprise an activation mechanism (such as a spring and/or gas cylinder), a chamber within said housing, and a plunger, vial, reservoir, needle, and/or retraction spring; wherein upon exit of the desired contents of the vial, the entire needle, reservoir, vial, and/or plunger assembly retracts towards the proximal end of housing by some means such as a wire, spring, o-ring, and/or rubber membrane and/or a needle protection portion slides over the needle following delivery of the medicament.

[182] A method for administering multiple pharmaceuticals is depicted in **FIG. 21**. The injector can include medicament selectors in order to allow the user to select which medicament to inject. The user can select the medicaments by sliding one or more selectors upward into their final position. An audible click or some other indicator may occur to alert the user to this final position. Moving the selector or multiple selectors upwards can allow a pin to snap into the plunger rod and/or into the pusher bar, which can create an entire portion that can push the vial system downwards and can inject the medication through the vial, the reservoir and/or needle. (This method can also be used with the Needleless injector method as described earlier in this document) Methods such as this embodiment could be extremely useful in applications

for anti-nerve agents or pain therapies. The device can also include a resilient material, such as rubber, to seal the selector openings and that can also slide within the housing once the selector is pushed upward. Once the aforementioned pins are in place, the device can function and activate similarly to that described above. A safety mechanism can be modified to eliminate the sliding selectors from being prematurely pushed upwards.

Exemplary Embodiment Seven: ***The Wet/Dry Injector***

[183] This exemplary embodiment can comprise a compact auto-injector that can have the ability to mix two or more medicaments in either a liquid or powder form to create one injectable medicament. The novel component of this device can be considered to be the use of a plurality of vials to deliver the medicament. The device also can comprise a needle protection system.

[184] An exemplary delivery system can comprise a housing, plurality of vials, plunger for each vial, a mixing activation mechanism, an activation chamber or vial, single needle or needle cannula, and/or a medicament or medicaments stored within each vial. Pre-injection, two or more medicaments can be stored separately in a vial and/or storage compartment and can communicate with each other once the mixing activation mechanism is initialized. The mixing activation mechanism could comprise a button, trigger, threaded rod, and or some other member that removes a piece or portion and/or punctures a piece or portion that is preventing each medicament to communicate with each other. The mixing activation mechanism may comprise a membrane, piece, and/or portion that may be removed pre-injection by the user in order to allow the separate vials and/or storage containers to communicate with each other. The mixing activation mechanism can be a piece that is manipulated in some way by the user in order to cause the contents of each compartment to mix with each other. This communication may occur by shaking the device and/or may occur automatically with the mixing activation mechanism. For instance, the mixing activation mechanism may cause each medicament to be released into an activation chamber, which may itself be a separate vial. This mixed medicament can be the medicament that will be injected into the patient. The delivery system further encompassing the mixed medicament vial or plurality

of mixed medicament vials in communication with the plunger(s) at the proximal end of the housing and in communication with a reservoir that can contain a single needle or needle cannula at the distal end; the needle can be protected by some sheath/ shield; the housing can further comprise a passage that is also in communication with the proximal end of the plunger such that when the spring(s) is activated from the distal or proximal end, a force can be applied through the passage on the plunger at the proximal end allowing for the plunger(s), vial(s), reservoir, and/or needle to travel towards the distal end of the housing; wherein the force provided can be caused by a spring, bar, contents from a gas cylinder, and/or other force mechanism; wherein the plunger can slideably travel through the vial towards the distal end to allow for the appropriate dose of medicament to be delivered; upon exit of the desired contents of the vial, the entire needle, reservoir, vial, and/or plunger assembly can retract towards the proximal end of housing by some means such as a wire, spring, o-ring, and/or rubber membrane and/or a needle protection portion slides over the needle following delivery of the medicament.

[185] **FIG. 22** depicts a novel method for injecting lyophilized medications, and/or powdered biologics that could need to be reconstituted pre-injection. **FIG. 22** shows a mechanism to mix and/or create an injectable medicament from two or more separate aforementioned substances. The figure depicts multiple vials that could have two substances in each vial separated by a pierceable membrane and/or other frangible piece. The vials in this embodiment can have one wet substance (such as sterilized water) and one dry substance (such as glucagons powder). The user can take off the safety tab which can prevent the user from accidental injection and/or pre-mature activation of the device. Once the safety device is removed, the user can twist and/or rotate the twisting portion at the top of the housing. By rotating this top portion, the rods attached to this portion (which can be threaded rods) can move downward. These rods can be located in the vials and/or through the pusher bar. The rods can have a sharp piercing portion on the distal end which can aid in puncturing the aforementioned pierceable membrane that can separate the substances in the vial. Once the piercing rod punctures the frangible and/or pierceable

membrane, the substances can mix together to form one medicament. The user can also shake the entire housing in order to aid in this mixing process.

Exemplary Embodiment Eight: ***Needle-End Safety System***

[186] Certain exemplary embodiments can comprise a safety system that can allow a user to remove some cap, bar, lock at the same end of an auto-injector housing where the needle is located. This can allow the device to be ready for activation while still protecting the needle at the same time. Many auto-injectors, such as most pen-like injectors, have the activation safety mechanism on the opposite end of where the needle is located. In an emergency situation, the user may mistake this safety cap as protecting the needle, when in fact this is not the case. There have been many documented cases of digital injection into a user's thumb or finger because of this reason. Having the safety mechanism at the same end of the needle can eliminate this risk.

Exemplary Embodiment Nine: ***Auto-injector with Feedback***

[187] The use of auto-injectors and drug delivery systems is common in the medical industry. Auto-injectors can deliver a range of medicaments into a patient, ranging from chronic therapies to critical care injectables. As more therapies are developed, the need for a vehicle to deliver these therapies is ever-increasing. Certain auto-injectors currently on the market can lack attributes that can allow the user to understand the device's functionality and/or operation. Thus, there is perceived a need for an auto-injector that can provide audible, haptic, and/or visual feedback to the user in order to effectively train and/or guide the user on how to properly operate the auto-injector and/or to mitigate user-related hazards that could occur when the device is not used correctly.

[188] The incidence of use-related hazards associated with auto-injectors is increasing. Common problems associated with certain injectors on the market include poor design, sharps exposure, and poor instruction. Many auto-injectors on the market are in the form of an apparatus that resembles a pen or marker. The safety mechanism for most of these devices can cause patient

confusion as it is often protecting the activation mechanism and not the location where the needle protrudes out of the device. There have been numerous cases of the user accidentally injecting the needle into their own thumb or finger because of this hazard. Examples of devices that incorporate this design can include certain pen-type auto-injectors for allergic emergencies, and/or certain anti-nerve agent auto-injectors currently supplied to both domestic and foreign militaries. These devices, and most auto-injectors on the market, also can allow the needle to remain protruding out after use, thereby potentially causing a post-injection sharps hazard. Further, many of these injectors exhibit poor instruction and/or labeling. Due to the cylindrical design of certain auto-injectors, the surface area for labeling can be small, rounded, and therefore can prevent a user from easily reading important information regarding the use of the device. For many injectors that are used in emergency situations, it can be important that the user be able to use the device correctly and efficiently. The user might not take or have time to read the instructions on the device during such a critical scenario.

[189] For one or more of these reasons, an interactive auto-injector or medical device is described that can provide a user with visual, haptic, and/or audible feedback in order to mitigate the aforementioned risks and/or to allow for easy injection of medications.

[190] Certain exemplary embodiments can provide an interactive auto-injector and/or a method of providing audible, haptic, and/or visual feedback to a user when operating the auto-injector. An auto-injector can be defined as any device that allows a user to deliver a medicament without having to manually prepare the injection. This can include pen delivered injectors, syringes, needleless injectors, gas powered auto-injectors, and/or any other auto-injector and/or medical device used to inject a pharmaceutical into a user/patient, etc.

[191] Certain exemplary embodiments can provide an auto-injector that can comprise an information device and/or system comprising at least one sensor (e.g., a pressure sensor, proximity sensor, tactile sensor, and/or biometric input device, etc.), switch (e.g., gate switch, microswitch, and/or pushbutton, etc.),

embedded system (e.g., microprocessor, memory, embedded operating system, system bus, input/output interface, and/or network interface, etc.), audible output sub-system (e.g., speaker, horn, buzzer, and/or piezoelectric transducer, etc.), visual output sub-system (e.g., flag, marker, light, liquid crystal display (LCD), light emitting diode (LED), optical fiber, organic polymer display, electric paper, screen, display, monitor, and/or tube, etc.), haptic output sub-system (e.g., buzzer, vibrator, bulging portion, tactile stimulator, cooler, and/or heater, etc.), and/or any other component and/or sub-system that would aid in providing audible, visual, and/or haptic feedback to a user of the auto-injector, along with appropriate circuitry, control system(s), housing(s), shielding, electrical conductors, and/or power source(s), etc.

[192] Certain embodiments of auto-injectors can comprise a housing, safety mechanism, activation mechanism (such as a spring means or compressed gas cylinder), a vial or container for storing the medicament, and a needle for delivering the medicament. Certain exemplary embodiments can provide one or more audible, visual, and/or haptic outputs to guide and/or instruct the user how to use the auto-injector properly. Sensors and/or switches can be placed on the safety tab, on the bottom of the device where the needle comes out, and/or where the inner sleeve slides up to activate the device. Visual outputs can be placed at each of the aforementioned locations as well and/or instead. An audible output sub-system can be placed anywhere on the device for audible feedback. A haptic output sub-system can be placed anywhere on the device. These electronically-triggered and/or active components and/or sub-systems can be incorporated into the labeling of the device and/or as a separate component to provide this visual, haptic, and/or audible feedback.

[193] For example, the user can push a button or switch on the device to initiate the audible, haptic, and/or visual output sub-system. A pre-recorded audible voice can tell the user to pull up on the safety tab, while a visual and/or haptic output can be rendered on the safety tab to provide a visual and/or haptic clue to the user as to where the safety tab is located. Once the safety tab is pulled up correctly, a sensor or switch could trigger the next step for the voice to announce, for example, asking the user to place the base of the device on the

outer portion of their thigh while also triggering a visual output to light the base of the device. By way of further example, the user can be provided a visual clue in which at least a portion of the base of the device is lighted and/or colored red, and/or the user can be provided a haptic clue in which the base on the device is moved and/or the base is heated sufficiently (such as to between approximately 105 degrees F and approximately 120 degrees F, including all values and sub-ranges therebetween) to substantially warm, yet not burn, the user's skin. The embedded operating system, which can run in hard real-time to avoid delays that might be significant and/or life-threatening, can also recognize a failure to complete a step in a certain specific timeframe and cause the step to be repeated if necessary and/or provide negative feedback if the user fails to perform a step properly (e.g., via input from a sensor or switch, the operating system can timely notice that the device is not placed on the skin of the thigh correctly and can cause the audible output sub-system to tell the user to repeat the placement step). Once the user places the device on the thigh properly, the sensor or switch could trigger the next audible, visual, and/or haptic clue and/or output, such as asking the user to push down on the outside sleeve of the device with force. By instructing the user step-by-step through each task, user error and/or risks of certain hazards can be reduced and/or eliminated.

[194] Certain exemplary embodiments can provide a compact, credit card-sized auto-injector used to deliver a variety of medicaments, such as pharmaceuticals and/or agents. Though this auto-injector can eliminate many problems associated with certain pen-style auto-injectors, such as the sharps hazard and/or the poor safety tab design, there can be a need for an interactive auto-injector in order to aid in user instruction of the device and/or to help ensure the device is used properly any and/or every time it is needed. The following, and the attached figures, further describes such an auto-injector.

[195] **FIG. 23** portrays an auto-injector having a housing similar to the length and width of a credit card, an activation mechanism on one side and a vial system non-coaxial with the activation mechanism. The activation mechanism can comprise a compressed spring and compressed gas cylinder used as the force

mechanism, and a puncturing mechanism to dispel the contents of the compressed gas cylinder. A vial system can be comprised of a pusher bar, plungers, vial(s)/medicament storage container(s), a reservoir, a needle, and a needle sheath. Retraction springs located at the base of the reservoir can push the needle back within the housing after injection. A slideable base can be used to activate the activation mechanism, which can be transparent to show the location of the aforementioned needle. A safety tab can be located between the base and the housing and/or can keep the activation mechanism from being activated while protecting the user from the needle. Sensors and/or switches, which can help trigger audible, haptic, and/or visual feedback, can be located on the base and/or on the safety tab. A button and/or switch, which can help trigger audible, haptic, and/or visual feedback sub-system(s), can be located on the housing. The feedback sub-system(s) can be activated based on inputs received and/or interpreted by the embedded operating system.

[196] For example, an audible output sub-system located in the housing can provide audible feedback to the user of the device. The audible output sub-system can be comprised of one or more piezoelectric transducers, small and/or large cones and/or speakers, sensors, capacitors, memories, power sources (e.g., battery, fuel cell, spring-actuated generator, etc.) housing, wires, and any other electronic components needed to provide recorded audible feedback to a user. The audible output sub-system can be activated by the aforementioned button or switch on the housing. The speaker can provide instructions for how the device is used and/or certain medication requirements.

[197] As another example, visual outputs can be located throughout the device, and/or on the base, safety tab, labeling, and/or housing to provide visual clues to the user. These visual outputs can be activated by the operating system once a sensor or switch is triggered. An LCD, optical polymer, LED, electric paper, and/or other form of display, monitor, and/or screen and/or other visual output can provide data to the user such as dosage amount, expiration date, instructions, Federal Drug Administration (FDA) requirements, and/or other labeling requirements, etc.

[198] Referring to **FIGS. 24 and 25**, the user can push the button on the housing to, via the embedded processor, activate the audible, haptic, and/or visual feedback sub-system on the auto-injector. For example, a voice from the audible output sub-system (now activated) can provide an audible message to the user, such as "Please remove the safety tab." The safety tab can also light up from visual outputs located on the safety tab. Once the safety tab is removed, a sensor can be triggered that can also trigger the next audible task from the audible output sub-system. If the safety tab is not removed within a certain timeframe, the first voice response can be repeated. The button or switch can be pressed several times or held in order to stop the process (in case the injector does not need to be used or the button was pressed accidentally). After the safety tab is removed, the next audible clue can be annunciated, such as "Please place the base of the device on the outer portion of your thigh." The base can simultaneously light up during this audible clue, providing a visual clue that demonstrates where the base is located and/or what portion of the base should be placed on the thigh. A sensor or switch, located on the base, can be used to help determine if the auto-injector is placed correctly on the injection site. The same switch and/or sensor, and/or another switch and/or sensor located on the base can help trigger the next audible message, such as "Push down on the top of the device to activate the injector." That switch and/or sensor can also trigger one or more visual outputs to light up the labeling and/or an arrow pointing down toward the injection site (as shown in **FIG. 24**).

[199] Certain exemplary embodiments can comprise a compact auto-injector that can have the ability to mix two or more medicaments, agents, solutes, solvents, etc., in either a liquid or powder form and/or create one injectable medicament. Certain exemplary embodiments can include an interactive system that can provide haptic, audible, and/or visual feedback to provide the user with instructions, hints, and/or clues in order to use the device properly. The auto-injector also can comprise a needle protection system.

[200] An exemplary delivery system can comprise a housing, plurality of vials, plunger for each vial, a mixing activation mechanism, an activation chamber or vial, single needle or needle cannula, and/or a medicament or medicaments stored within each vial, etc. Prior to injection, two or more medicaments can be stored separately in a vial and/or storage compartment and can fluidically communicate with each other once the mixing activation mechanism is initialized. The mixing activation mechanism can comprise a button, trigger, threaded rod, and or some other member that removes a piece or portion and/or punctures a piece or portion that is preventing each medicament from communicating with each other. The mixing activation mechanism can comprise a membrane, piece, and/or portion that can be removed pre-injection by the user in order to allow the separate vials and/or storage containers to fluidically communicate with each other. The mixing activation mechanism can be a piece that is manipulated in some way by the user in order to cause the contents of each compartment to mix with each other. This communication can occur by shaking the device and/or can occur automatically with the mixing activation mechanism. For instance, the mixing activation mechanism can cause each medicament to be released into an activation chamber, which may itself can be a separate vial. This mixed medicament can be the medicament that will be injected into the patient.

[201] The delivery system can comprise the mixed medicament vial or plurality of mixed medicament vials in mechanical and/or fluid communication with the plunger(s) at the proximal end of the housing and in mechanical and/or fluid communication with a reservoir that can contain a single needle or needle cannula at the distal end. The needle can be protected by a sheath and/or shield. The housing can comprise a passage that is also in mechanical and/or fluid communication with the proximal end of the plunger such that when the spring(s) is activated from the distal or proximal end, a force can be applied through the passage on the plunger at the proximal end allowing for the plunger(s), vial(s), reservoir, and/or needle to travel towards the distal end of the housing. The applied force can be caused by a spring, bar, contents from a gas cylinder, and/or other force mechanism. The plunger can slideably travel through the vial towards the distal end to allow for the appropriate dose of

medicament to be delivered. Upon exit of the desired contents of the vial, the entire needle, reservoir, vial, and/or plunger assembly can retract towards the proximal end of housing by some means such as a wire, spring, o-ring, and/or rubber membrane and/or a needle protection portion slides over the needle following delivery of the medicament.

[202] The interactive system can comprise a speaker sub-system that can comprise piezos and/or other components to produce audible sounds and/or human voice; a haptic sub-system that can provide haptic feedback to the user; a visual sub-system that can comprise light emitting diodes, LCD's, optical fibers, and/or other components that can produce visual outputs such as light and/or color; a processor that can be used to control the activation of such components; a power source such as a battery that can power the aforementioned interactive system; and/or switches, buttons, and/or sensors that can activate certain visual, haptic, and/or audible clues at a particular moment.

[203] **FIG. 25** depicts a novel method for injecting lyophilized medications, and/or powdered biologics that might need to be reconstituted pre-injection. **FIG. 25** shows a mechanism to mix and/or create an injectable medicament from two or more separate aforementioned substances. **FIG. 25** depicts multiple vials that can have, for example, at least two substances in each vial separated by one or more pierceable membranes and/or other frangible pieces. The vials can have at least one wet substance (such as sterilized water) and at least one dry substance (such as glucagon powder). The user can take off the safety tab, which can prevent the user from accidental injection and/or pre-mature activation of the device. Once the safety tab and/or device is removed, the user can twist and/or rotate the twisting portion at the top of the housing. By rotating this top portion, the rods attached to this portion (which can be threaded rods) can move downward. These rods can be located in the vials and/or through the pusher bar. The rods can have a sharp piercing portion on the distal end which can aid in puncturing the aforementioned pierceable membrane(s) that can separate the substances in the vial. Once the piercing rod punctures the frangible and/or pierceable membrane(s), the substances

previously separated thereby can mix together to form one medicament. The user can also shake the entire housing in order to aid in this mixing process.

[204] The device can include an electronic/interactive system to provide visual, haptic, and/or audible feedback to the user. This interactive system can include a microprocessor to control the specific feedback components, a speaker sub-system, a haptic sub-system, a sub-system of switches and/or sensors, a sub-system of LEDs or optics, a battery power source, and any other component needed to produce audible or visual outputs. Figure 4 portrays these components located throughout the device; however, the actual placement of these components is flexible. The user can activate the interactive system by pushing a button or switch located on the housing of the device. This button or switch can activate the processor which can then send signals to the audible output sub-system, haptic output sub-system, and/or visual output sub-system. The audible output sub-system can provide an audible clue for the initial task, which can be in the form of a human, humanesque, and/or understandable voice stating, "Please remove the safety tab." A signal can also be sent simultaneously to the safety tab visual output (potentially one or more LEDs) to provide a visual light and/or color clue to the user as to where the safety tab is located. Once the safety tab is removed, a switch or sensor can send a signal to the processor and activate the next audible, haptic, and/or visual clue. This can be a human voice that states "Please twist the top portion of the injector to activate the mixing mechanism." As with the safety tab, an LED or some other visual clue then can be activated, lighting up the mixing activation mechanism, and/or a haptic clue can be activated, such as vibrating, warming, cooling, bulging, moving, changing a texture of, etc., the mixing activation mechanism. A switch or sensor located near or on the mixing activation mechanism can be used to ensure that the mixing was complete and to trigger the next audible and/or visual clue by the processor. A voice next can state, "Please shake gently to mix the solution." After a certain amount of time, the processor then can send a signal to the audible output sub-system for the next task. This can be a voice that says, "Please place the injector on the outer portion of your thigh." A visual indicator of where the base/injector should be placed also can be simultaneously activated. A switch, sensor, or button then

can recognize the correct placement of the device and trigger the next audible and visual clue. This can be a voice stating, "Push down on the top of the injector to activate the injection." Likewise, an arrow or some other visual and/or haptic clue can light up and/or be rendered to show the motion of how the injector should be pushed. The last clue can be an audible clue that states, "Hold in place for several seconds, remove, and dispose of properly," indicating that the injection is complete. Additional audible, haptic, and/or visual feedback sub-systems can be used to provide the user with important information such as the expiration of the drug, improper use, and/or error. For instance, the device's LEDs or optics can blink, a display can render a message, a vibrator can vibrate, and/or an audible beep and/or voice can be activated after a particular time stamp is reached that corresponds to the expiration of the drug and/or device. As another example, once an auto-injector has been used, a message can be displayed describing proper disposal and/or recycling techniques.

[205] **FIG. 26** is a block diagram of an exemplary embodiment of an information system and/or device 26000, which in certain operative embodiments can comprise, for example, the interactive, integral, embedded, audible, haptic, and/or visual feedback system, such as described herein. Information system and/or device 26000 can comprise any of numerous components, such as for example, one or more network interfaces 26100, one or more processors 26200 running an embedded, real-time, hard real-time, and/or soft real-time operating system, one or more memories 26300 containing instructions 26400, one or more input/output (I/O) devices 26500, and/or one or more user interfaces 26600 coupled to I/O device 26500, etc.

[206] In certain exemplary embodiments, via one or more user interfaces 26600, such as a graphical user interface, a user can view a rendering of information related to selecting, purchasing, obtaining, operating, maintaining, re-using, and/or disposing of an auto-injector. In certain exemplary embodiments, instructions 26400 can be modified and/or updated via replacing a removable memory 26300 and/or via replacing instructions 26400 (such as, e.g., via flashing an EEPROM, etc.). In certain exemplary embodiments, instructions

26400 can be modified and/or updated via downloading replacement instructions via network interface 26100. System 26000 can comprise a programmable logic controller.

[207] Still other practical and useful embodiments will become readily apparent to those skilled in this art from reading the above-recited detailed description and drawings of certain exemplary embodiments. It should be understood that numerous variations, modifications, and additional embodiments are possible, and accordingly, all such variations, modifications, and embodiments are to be regarded as being within the spirit and scope of this application.

[208] Thus, regardless of the content of any portion (e.g., title, field, background, summary, abstract, drawing figure, etc.) of this application, unless clearly specified to the contrary, such as via an explicit definition, assertion, or argument, with respect to any claim, whether of this application and/or any claim of any application claiming priority hereto, and whether originally presented or otherwise:

[209] there is no requirement for the inclusion of any particular described or illustrated characteristic, function, activity, or element, any particular sequence of activities, or any particular interrelationship of elements;

[210] any elements can be integrated, segregated, and/or duplicated;

[211] any activity can be repeated, performed by multiple entities, and/or performed in multiple jurisdictions; and

[212] any activity or element can be specifically excluded, the sequence of activities can vary, and/or the interrelationship of elements can vary.

[213] Accordingly, the descriptions and drawings are to be regarded as illustrative in nature, and not as restrictive. Moreover, when any number or range is described herein, unless clearly stated otherwise, that number or range is approximate. When any range is described herein, unless clearly stated otherwise, that range includes all values therein and all subranges therein. Any information in any material (e.g., a United States patent, United States patent application, book, article, etc.) that has been incorporated by reference herein, is only incorporated by reference to the extent that no conflict exists between such information and the other statements and drawings set

forth herein. In the event of such conflict, including a conflict that would render invalid any claim herein or seeking priority hereto, then any such conflicting information in such incorporated by reference material is specifically not incorporated by reference herein.

Claims:

1. An auto-injector, comprising:

a vial configured to store an injectable medicament, said vial defining a vial longitudinal axis;

a non-electronic force initiator configured to produce a force to inject the injectable medicament, said non-electronic force initiator defining a force initiator longitudinal axis located non-co-axially with the vial longitudinal axis;

a housing comprising said vial; and

an electronic output device coupled to said housing and configured to output an electronic indication, said electronic indication one of a group of electronic indications automatically triggerable by a microprocessor, the electronic indication not associated with a quantity of the injectable medicament, the electronic indication associated with at least two of:

auto-injector replacement;
medicament mixing;
injection delay;
safety guard removal;
auto-injector positioning;
auto-injector orientation;
actuator location;
injection hazard avoidance;
injection duration;
injection status;
injection error;
auto-injector removal;
auto-injector reuse;
auto-injector recycling; and
auto-injector disposal.

2. The auto-injector of claim 1, wherein said housing defines a length and width approximating a credit card and a thickness of less than one inch.

3. The auto-injector of claim 1, wherein the electronic output device is configured to output the electronic indication in response to a sensor input.

4. The auto-injector of claim 1, wherein the electronic output device is configured to output the electronic indication in response to a user input.

5. The auto-injector of claim 1, wherein the electronic output device is configured to output the electronic indication in response to a determination of a hazardous condition.

6. The auto-injector of claim 1, wherein the electronic indication is a visual output.

7. The auto-injector of claim 1, wherein the electronic indication is an audible output.

8. The auto-injector of claim 1, wherein the electronic indication is a haptic output.

9. The auto-injector of claim 1, wherein the electronic indication is a verbal output.

10. The auto-injector of claim 1, wherein the electronic output device includes at least one of a speaker, a display, a light emitting diode, a vibrator and a heater.

11. The auto-injector of claim 1, wherein the electronic output device includes:

the microprocessor configured to produce a signal associated with the electronic indication; and

a sensor in electronic communication with the microprocessor, the microprocessor configured to produce the signal in response to an input received from the sensor.

12. The auto-injector of claim 1, wherein the electronic output device includes a switch, the electronic output device configured to output the electronic indication when the switch is moved from a first switch state to a second switch state.

13. The auto-injector of claim 1, wherein the non-electronic force initiator includes a gas container.

14. The auto-injector of claim 1, wherein the housing defines a channel adapted to convey the at least a portion of the medicament from said vial to a needle.

15. The auto-injector of claim 1, wherein said injectable medicament is a liquid.

16. The auto-injector of claim 1, wherein said injectable medicament is a mixture of a liquid and a solid.

17. The auto-injector of claim 1, further comprising a spring adapted to retract a needle fluidly coupled to said vial.

18. The auto-injector of claim 1, further comprising a releasable actuation lock adapted to prevent accidental activation of said auto-injector.

19. A processor readable medium storing code representing instructions to cause a processor to perform a process, the code comprising code to:

via an output device of an auto-injector, render a use indication, said use indication one of a group of use indications automatically triggerable by a microprocessor, said group not regarding a quantity of the injectable medicament, said group regarding at least two of:

auto-injector replacement;

medicament mixing;

injection delay;

safety guard removal;

auto-injector positioning;

auto-injector orientation;

actuator location;

injection hazard avoidance;

injection duration;

injection status;

injection error;

auto-injector removal;

auto-injector reuse;

auto-injector recycling; and

auto-injector disposal;

said auto-injector comprising:

a vial configured to store an injectable medicament, said vial defining a vial longitudinal axis;

a force initiator configured to supply a driving force to the injectable medicament, said force initiator defining a force initiator longitudinal axis located non-co-axially with the vial longitudinal axis; and

a housing comprising said vial, said output device coupled to said housing.

20. An apparatus, comprising:

an auto-injector configured to deliver only a single dose of a medicament into a body, the auto-injector including

a housing;

a medicament container disposed within the housing, the medicament container configured to contain the single dose of the medicament;

an activation mechanism including a non-electronic energy storage member configured to produce a force to deliver the single dose of the medicament; and

an electronic circuit system configured to be coupled to the housing, the electronic circuit system configured to output an electronic output when the activation mechanism is actuated.

21. The apparatus of claim 20, wherein the electronic circuit system is further configured to output a signal associated with at least one of a visual output, an audible output, a thermal output or a vibratory output.

22. The apparatus of claim 20, wherein the electronic output includes a verbal output.

23. The apparatus of claim 20, wherein the electronic output includes recorded speech.

24. The apparatus of claim 20, wherein the electronic output includes an instruction for using the auto-injector.

25. The apparatus of claim 20, wherein:

the activation mechanism is configured to be actuated by manually manipulating an actuator; and

the electronic circuit system is configured to output includes a visual indicia adjacent the actuator.

26. The apparatus of claim 20, wherein the electronic output is associated with any one of a status of the auto-injector, an expiration date associated with the medicament or a position of the auto-injector.

27. The apparatus of claim 20, wherein:

the electronic output is a first electronic output;

the auto-injector further includes a locking member movably coupled to the housing, the locking member configured to engage a portion of the actuator to prevent actuation of the activation mechanism ; and

the electronic circuit system includes a switch operably coupled to the locking member such that the locking member actuates the switch when the locking member is moved, the electronic circuit system is configured to output a second electronic output when the locking member lock actuates the switch.

28. The apparatus of claim 20, wherein:

the electronic circuit system includes a switch having a first state and a second state, the switch is operably coupled to the actuator such that the actuator actuates the switch when the actuator is moved; and

the electronic circuit system is configured to output the electronic output when the switch is changed from the first state to the second state.

29. The apparatus of claim 20, wherein:

the electronic circuit system includes a sensor; and

the electronic circuit system is configured to output the electronic output in response to an input received from the sensor.

30. The apparatus of claim 20, wherein the electronic circuit system includes at least one of a processor, a memory component, a sensor, a switch or a battery.

31. The apparatus of claim 20, wherein the electronic circuit system includes at least one of a speaker, a light-emitting diode, a liquid crystal display, an organic polymer display, a fiber optic display, a vibrator, a heater, a cooler or a piezo-electric transducer.

32. The apparatus of claim 20, wherein the non-electronic energy storage member is any one of a spring or a pressurized gas container.

33. The apparatus of claim 20, wherein:

the auto-injector further includes a label configured to be coupled to the housing; and

at least a portion of the electronic circuit system is incorporated into the label.

34. The apparatus of claim 20, wherein the auto-injector further includes a needle configured to be in fluid communication with the medicament container, the needle configured to be moved between a first position and a second position, in the first position the needle is contained within the housing, in the second position a portion of the needle extends from the housing.

35. An apparatus, comprising:

a housing;

an activation mechanism disposed within the housing, the activation mechanism configured to produce a force to inject a dose of medicament contained within the housing into a body;

an actuator configured to be manipulated by a user to actuate the activation mechanism; and

an electronic circuit system coupled to the housing, the electronic circuit system including a speaker and a visual output device adjacent to the actuator, the electronic circuit system configured to output a recorded speech output via the speaker and a visual output via the visual output device to collectively identify a location of the actuator.

36. The apparatus of claim 35, wherein the recorded speech output is a first recorded speech output, the electronic circuit system configured to output a second recorded speech output in response to the manipulation of the actuator.

37. The apparatus of claim 35, wherein the visual output includes a visual text message produced on a display screen.

38. The apparatus of claim 35, wherein the electronic circuit system is further configured to output a haptic output.

39. The apparatus of claim 35, further comprising a locking member configured to engage a portion of the actuator to prevent actuation of the activation mechanism, the electronic circuit system including a switch operably coupled to the locking member such that the locking member actuates the switch when the locking member is moved, the electronic circuit system configured to produce at least one of the recorded speech output or the visual output when the locking member is moved relative to the housing.

40. The apparatus of claim 35, wherein:

the electronic circuit system includes a switch having a first state and a second state; and

the electronic circuit system is configured to produce at least one of the recorded speech output or the visual output when the switch is changed from the first state to the second state.

41. The apparatus of claim 35, wherein:

the electronic circuit system includes a sensor; and

the electronic circuit system is configured to produce at least one of the recorded speech output or the visual output in response to an input received from the sensor.

42. The apparatus of claim 35, wherein the recorded speech output includes any one of an instruction for using the apparatus, an indication of a status of the apparatus, an indication of an expiration date associated with a medicament contained within the housing or an indication of a position of the apparatus.

43. The apparatus of claim 35, further comprising:

a medicament container disposed within the housing, the medicament container configured to contain only a single dose of the medicament; and

a needle configured to be placed in fluid communication with the medicament container such that the single dose of the medicament can be injected into a body through the needle in response to actuation of the activation mechanism.

44. An apparatus, comprising:

a medicament delivery device configured to deliver a medicament into a body, the medicament delivery device including:

a housing;

medicament container disposed within the housing, the medicament container configured to contain the medicament;

a delivery mechanism configured to produce a force to deliver the medicament into the body;

a safety lock configured to engage a portion of the delivery mechanism to prevent actuation of the delivery mechanism; and

an electronic circuit system configured to be coupled to the housing, the electronic circuit system configured to output a plurality of recorded speech instructions, the electronic circuit system including a switch operably coupled to the safety lock such that the safety lock actuates the switch when the safety lock is moved, the electronic circuit system configured to output a first recorded speech instruction from the plurality of recorded speech instructions when the switch is actuated.

45. The apparatus of claim 44, wherein the plurality of recorded speech instructions is output in a predetermined sequence.

46. The apparatus of claim 44, wherein the plurality of recorded speech instructions is output in a sequence determined based on input received from any one of the switch, a sensor or a timer.

47. The apparatus of claim 44, wherein:

the medicament delivery device includes an actuator configured to actuate the delivery mechanism;

the electronic circuit system includes a light output device adjacent the actuator, the electronic circuit system configured to produce a light output via the light output device when the switch is actuated; and

the first recorded speech instruction identifies a location of the actuator.

48. The apparatus of claim 44, wherein the electronic circuit system is configured to produce a second recorded speech output from the plurality of recorded speech instructions when the delivery mechanism is actuated.

49. The apparatus of claim 44, wherein the plurality of recorded speech instructions includes an instruction associated with activation of a mixing mechanism configured to mix the medicament contained in the medicament container.

50. The apparatus of claim 44, wherein the plurality of recorded speech instructions includes an instruction associated with positioning the medicament delivery device adjacent the body.

51. The apparatus of claim 44, wherein the plurality of recorded speech instructions includes an instruction associated with actuation of the medicament delivery device.

52. The apparatus of claim 44, wherein the electronic circuit system includes at least one of a processor, a memory component, a sensor, a switch or a battery.

53. The apparatus of claim 44, wherein the electronic circuit system includes at least one of a speaker, a light-emitting diode, a liquid crystal display, an organic polymer display, a fiber optic display, a vibrator, a heater, a cooler or a piezo-electric transducer.

54. The apparatus of claim 44, wherein:

the medicament delivery device further includes a label configured to be coupled to the housing; and

at least a portion of the electronic circuit system is incorporated into the label.

55. The apparatus of claim 44, wherein

the plurality of recorded speech instructions is a first plurality of recorded speech instructions; and

the electronic circuit system is further configured to output a second plurality of recorded speech instructions associated with an event subsequent to the use of the medicament delivery device.

56. The apparatus of claim 44, wherein the medicament delivery device is configured to automatically inject the medicament into the body.

57. An apparatus, comprising:

a medicament delivery device configured to deliver a medicament into a body, the medicament delivery device including:

a housing;

medicament container disposed within the housing, the medicament container configured to contain the medicament;

a delivery member coupled to the medicament container, the delivery member configured to convey the medicament into the body in response to the manipulation of an actuator;

an electronic circuit system including a visual output device and a switch operably coupled to the actuator such that the switch is actuated when the actuator is manipulated, the electronic circuit system configured to produce a visual output via the visual output device when the switch is actuated; and

a label disposed on an exterior surface of the housing, the label including at least a portion of the electronic circuit system including the switch and the visual output device.

58. The apparatus of claim 57, wherein the medicament delivery device is configured to deliver only a single dose of the medicament.

59. The apparatus of claim 57, wherein the electronic circuit system is configured to produce a recorded speech output.

60. The apparatus of claim 57, wherein the electronic circuit system is configured to produce an instruction associated with the use of the medicament delivery device.

61. The apparatus of claim 57, wherein the electronic circuit system includes a processor, a memory component, a light-emitting diode and a switch.

62. The apparatus of claim 57, wherein the delivery member includes a needle configured to be in fluid communication with the medicament container, the needle configured to be moved between first position and a second position, in the first

position the needle is contained within the housing, in the second position a portion of the needle extends from the housing.

63. The apparatus of claim 57, wherein the medicament delivery device is configured to automatically inject the medicament into the body.

64. An apparatus, comprising:

a medicament delivery device configured to deliver a medicament into a body, the medicament delivery device including:

a movable safety lock configured to prevent actuation of the medicament delivery device when in a first position;

a sensor configured to produce a signal when disposed adjacent to the body; and

an electronic circuit system operatively coupled to the safety lock and the sensor, the electronic circuit system configured to produce an electronic output in response to the signal produced by the sensor.

65. The apparatus of claim 64, wherein the electronic output includes a signal associated with recorded speech.

66. The apparatus of claim 64, wherein the electronic output includes an instruction associated with the use of the medicament delivery device.

67. The apparatus of claim 64, wherein the medicament delivery device is configured to automatically inject the medicament into the body.