

**DRUG DELIVERY DEVICE HAVING A NEEDLE SHIELD WITH VISUAL FEEDBACK****CROSS-REFERENCE TO RELATED APPLICATION**

**[0001]** The present application claims priority to U.S. Provisional Patent Application No. 63/518,266, filed August 8, 2023, the entire contents of which are hereby incorporated by reference herein.

**FIELD OF DISCLOSURE**

**[0002]** The present disclosure relates to drug delivery devices, and, more particularly, devices for automatically injecting a drug into a patient that have needle guard mechanisms that are retractable to effect needle insertion and dose administration.

**BACKGROUND**

**[0003]** A general aversion to exposed needles, as well as health and safety issues, have led to the development of drug delivery devices which conceal a needle or other insertion member prior to use and which automate various aspects of an injection process. For example, a drug delivery device, such as injectors and autoinjectors, may incorporate various health and safety features to protect the injection needles from exposure and protect against risks of accidental needle stick or unintended dose delivery. Such features may include a retractable needle guard to cover a needle in a pre-delivery and/or post-delivery state. Typically, such retractable needle guard requires an input force by the user to expose the injection needle and effect needle insertion. For instance, after placing the needle guard in contact with the user's skin, the user may need to exert a certain amount of force against the needle guard to retract the needle guard, expose the injection needle, and effect needle insertion.

**[0004]** Often times, however, the user may not know when to stop applying additional force against the needle guard (i.e., when the needle is sufficiently inserted into the user's skin). Additionally, the user may not know when to maintain the input force exerted against the needle guard to ensure that the needle is properly inserted in the user's skin throughout the duration of the injection. This, in turn, can make it difficult for the user to self-administer a drug and can increase the likelihood of improper dose administration. As the demand grows for drug delivery devices with greater ease of use and safety, finding a way to incorporate more features without adding undue complexity to the drug delivery device presents various design and manufacturing challenges.

**[0005]** The present disclosure sets forth drug delivery devices embodying advantageous alternatives to existing drug delivery devices, and that may address one or more of the challenges or needs mentioned herein.

**SUMMARY**

**[0006]** One aspect of the present disclosure provides a drug delivery device comprising a housing, a drug storage container, a plunger, and a guard. The housing may define a longitudinal axis and may have an opening. The drug storage container may include a delivery

member having an insertion end configured to extend at least partially through the opening during a delivery state. The plunger may be moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member. The guard may be disposed adjacent the opening in the housing and may be moveable relative to the housing between an extended position and a retracted position. The insertion end of the delivery member may be surrounded by the guard in the extended position and the insertion end may be at least partially exposed in the retracted position. The guard may include a first annular portion and a second annular portion disposed at a distal end of the first annular portion, and the second annular portion may have an outer diameter greater than an outer diameter of the first annular portion. The second annular portion may be positioned a first distance from a distal end of the housing when the guard is in the extended position and the second annular portion may be positioned a second distance from the distal end of the housing when the guard is in the retracted position. The second distance may be smaller than the first distance.

**[0007]** In some embodiments, the second annular portion may be defined by an annular side wall, a bottom wall configured to contact a skin of a user, and a top wall opposite the bottom wall. In some embodiments, the top wall may include a first ramped surface, and the distal end of the housing may include a second ramped surface that is complementary to the first ramped surface. In other embodiments, the top wall may include a first stepped surface, and the distal end of the housing may include a second stepped surface that is complementary to the first stepped surface. In yet another embodiment, the top wall may include a first curved surface, and the distal end of the housing may include a second curved surface that is complementary to the first corrugated surface.

**[0008]** In some embodiments, at least a portion of the annular side wall of the first annular portion may be configured to slide within the housing when the guard is in the retracted position. In some embodiments, the outer diameter of the second annular portion may be substantially the same as an outer diameter of the housing. In other embodiments, the outer diameter of the second annular portion may be smaller than an outer diameter of the housing. In some embodiments, the first annular portion of the guard may be at least partially defined by an annular side wall, and the annular side wall of the first annular portion may be configured to slide within the housing between the extended position and the retracted position. In some embodiments, the second annular portion may be coupled to the first annular portion. In other embodiments, the first annular portion and the second annular portion may be defined by a single, monolithic structure.

**[0009]** In some embodiments, the drug delivery device may further comprise a plunger guide fixed relative to the housing, and the plunger may be disposed at least partially within the plunger guide. The drug delivery device may further comprise a releaser member operably coupled to the plunger and configured to selectively rotate relative to the housing. Each of the plunger and the plunger guide may be disposed at least partially within the releaser member.

The guard may be operably coupled to the releaser member. In some embodiments, the releaser member may be prevented from rotating in at least one rotational direction when the guard is in the extended position, and the releaser member may be allowed to rotate in the at least one rotational direction when the guard is in the retracted position. In some embodiments, moving the guard from the extended position to the retracted position may allow the releaser member and the plunger to rotate jointly from a first rotational position toward a second rotational position under a biasing force exerted by a biasing member.

**[0010]** In some embodiments, the drug delivery device may further comprise a lock ring configured to rotate between a first rotational position and a second rotational position. A rotational position of the lock ring may be based on an axial position of the guard. In some embodiments, a distal end of the lock ring may be disposed at least partially within the guard. The drug delivery device may further comprise a lock ring biasing member positioned between the lock ring and a bottom wall of the second annular portion of the guard. The lock ring biasing member may be positioned within the first annular portion of the guard. In some embodiments, the lock ring biasing member may be a compression spring configured to exert a biasing force on the guard to urge the guard toward the extended position.

**[0011]** According to another embodiment of the present disclosure, a method of delivering a drug is provided. The method comprises providing a drug delivery device including a housing, a drug storage container having a delivery member with an insertion end, a plunger moveable toward a distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, and a guard moveable relative to the housing between an extended position and a retracted position. The guard may include a first annular portion and a second annular portion disposed at a distal end of the first annular portion, and the second annular portion may have an outer diameter greater than an outer diameter of the first annular portion. The method also comprises placing the drug delivery device such that the second annular portion of the guard abuts an injection site and applying a force to the housing toward the injection site to permit movement of the guard from the extended position to the retracted position. The second annular portion may be positioned a first distance from a distal end of the housing when the guard is in the extended position and the second annular portion may be positioned a second distance from the distal end of the housing when the guard is in the retracted position, the second distance being smaller than the first distance.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[0012]** It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the drawings may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some drawings are not necessarily indicative of the presence or absence of particular elements in any of the exemplary

embodiments, except as may be explicitly delineated in the corresponding written description.

Also, none of the drawings is necessarily to scale.

**[0013]** Fig. 1A illustrates a perspective view of a drug delivery device.

**[0014]** Fig. 1B illustrates a perspective view of the drug delivery device of Fig. 1A, with a cap removed therefrom.

**[0015]** Fig. 1C illustrates a perspective view of the drug delivery device of Fig. 1A, in a pre-injection configuration.

**[0016]** Fig. 1D illustrates a perspective view of the drug delivery device of Fig. 1A, in an injection configuration.

**[0017]** Fig. 2 illustrates cross-sectional view of the drug delivery device of Figs. 1A-1D.

**[0018]** Fig. 3A illustrates a front view of an exemplary drug delivery device, in a pre-injection configuration, in accordance with various embodiments of the present disclosure.

**[0019]** Fig. 3B illustrates a front view of the exemplary drug delivery device of Fig. 3A, in an injection configuration, in accordance with various embodiments of the present disclosure.

**[0020]** Fig. 3C illustrates a perspective view of the exemplary drug delivery device of Fig. 3A, in accordance with various embodiments of the present disclosure.

**[0021]** Fig. 3D illustrates a perspective view of the exemplary drug delivery device of Fig. 3B, in accordance with various embodiments of the present disclosure.

**[0022]** Fig. 4A illustrates a front view of another exemplary drug delivery device, in a pre-injection configuration, in accordance with various embodiments of the present disclosure.

**[0023]** Fig. 4B illustrates a front view of the exemplary drug delivery device of Fig. 4A, in an injection configuration, in accordance with various embodiments of the present disclosure.

**[0024]** Fig. 5 illustrates two different views of an exemplary needle shield, in accordance with various embodiments of the present disclosure.

**[0025]** Fig. 6A illustrates a front view of another exemplary drug delivery device, in a pre-injection configuration, in accordance with various embodiments of the present disclosure.

**[0026]** Fig. 6B illustrates a front view of the exemplary drug delivery device of Fig. 6A, in an injection configuration, in accordance with various embodiments of the present disclosure.

**[0027]** Fig. 6C illustrates two different views of an exemplary needle shield of the exemplary drug delivery device of Fig. 6A, in accordance with various embodiments of the present disclosure.

**[0028]** Fig. 7A illustrates a front view of another exemplary drug delivery device, in a pre-injection configuration, in accordance with various embodiments of the present disclosure.

**[0029]** Fig. 7B illustrates a front view of the exemplary drug delivery device of Fig. 7A, in an injection configuration, in accordance with various embodiments of the present disclosure.

**[0030]** Fig. 7C illustrates two different views of an exemplary needle shield of the exemplary drug delivery device of Fig. 7A, in accordance with various embodiments of the present disclosure.

**DETAILED DESCRIPTION**

**[0031]** The present disclosure generally relates to drug delivery devices operable by a user for administering a drug, or in the case where a patient is the user, self-administering a drug. Various features are disclosed such as a needle guard with one or more indicators for signaling to the user when to stop further pressing the drug delivery device against the user's skin and/or when to hold the user's force exerted on the drug delivery device. These features and others work together and/or interact with one another to limit the complexity of the drug delivery device and to ensure proper drug delivery. For example, the drug delivery device does not require or include an independent component for signaling to the user when the user should stop pressing the drug delivery device against the user's skin, thereby reducing the mechanical complexity, durability, and/or cost of the device. These and other advantages will be apparent to one of ordinary skill in the art reviewing the present disclosure. As used herein, the term "guard member" is generally referring to a guard for protecting the insertion end of the delivery member (e.g., needle) and is used interchangeably with a "needle shield" or a "needle guard."

**[0032]** Figs. 1A-1D and 2 illustrate several views of a drug delivery device 10 for delivering a drug, which may also be referred to herein as a medicament or drug product. The drug may be, but is not limited to, various biologicals such as peptides, peptibodies, or antibodies. The drug may be in a fluid or liquid form, although the disclosure is not limited to a particular state.

**[0033]** Various implementations and configurations of the drug delivery device 10 are possible. The drug delivery device 10 may be configured as a single-use, disposable injector. In other embodiments, the drug delivery device 10 may be configured as multiple-use reusable injector. The drug delivery device 10 may be operable for self-administration by a patient or for administration by caregiver or a formally trained healthcare provider (e.g., a doctor or nurse). The drug delivery device 10 may take the form of an autoinjector or pen-type injector, and, as such, may be held in the hand of the user over the duration of drug delivery.

**[0034]** The configuration of various components included in the drug delivery device 10 may depend on the operational state of the drug delivery device 10. The drug delivery device 10 may have a pre-injection or storage state (shown in Figs. 1A-1C), an injection or dosing state (shown in Fig. 1D), and a post-injection state, although fewer or more states are also possible. The pre-injection state may correspond to the configuration of the drug delivery device 10 subsequent to assembly and prior to activation by the user. In some embodiments, the pre-injection state may exist in the time between when the drug delivery device 10 leaves a manufacturing facility and when a patient or user activates a drive mechanism 30 of the drug delivery device 10. This includes the moments in time after the user has removed the drug delivery device 10 from any secondary packaging and prior to positioning the drug delivery device 10 against the injection site. The injection state may correspond to the configuration of the drug delivery device 10 while drug delivery, also referred to herein as dosing, is in progress. The post-injection state may correspond to the configuration of the drug delivery device 10 after

drug delivery is complete and/or when a stopper is arranged in an end-of-dose position in a drug storage container.

**[0035]** As shown in Figs. 1A and 1B, the drug delivery device 10 includes an outer casing or housing 12. In some embodiments, the housing 12 may be sized and dimensioned to enable a person to grasp the injector 10 in a single hand. The housing 12 may have a generally elongate, tubular shape, such as a cylindrical shape, and extend along a longitudinal axis A between a proximal end and a distal end of the housing 12. In some embodiments, an outer diameter of the housing 12 may be the same from a proximal end to a distal end thereof along the longitudinal axis A. In other embodiments, the outer diameter of the housing 12 may vary along the longitudinal axis A such that the outer diameter of the housing 12 proximate the distal end thereof may be greater than the outer diameter of the housing 12 proximate the proximal end thereof. An opening 14 (Fig. 2) may be formed in the distal end to permit an insertion end 28 of a delivery member 16 (Fig. 2) to extend outside of the housing 12. A transparent or semi-transparent inspection window 17 (Figs. 1A and 1B) may be positioned in a wall of the housing 12 to permit a user to view component(s) inside the drug delivery device 10, including a drug storage container 20. Viewing the drug storage container 20 through the window 17 may allow a user to confirm that drug delivery is in progress and/or complete. A removable cap 19 may cover the opening 14 prior to use of the drug delivery device 10, and, in some embodiments, may including a gripper 13 (Fig. 2) configured to assist with removing a sterile barrier 21 (e.g., a rigid needle shield (RNS), a non-rigid needle shield (nRNS), etc.) mounted on the insertion end 28 of the delivery member 16. The gripper 13 may include one or more inwardly protruding barbs or arms that frictionally or otherwise mechanically engage the sterile barrier 21 to pull the sterile barrier 21 with the removable cap 19 when the user separates the removable cap 19 from the housing 12. Thus, removing the removable cap 19 has the effect of removing the sterile barrier 21 from the delivery member 16.

**[0036]** As shown in Fig. 2, the drive mechanism 30 may be disposed partially or entirely within the housing 12. Generally, the drive mechanism 30 may be configured to store energy and, upon or in response to activation of the drive mechanism 30 by the user, release or output that energy to drive the plunger 26 (also referred to as "plunger rod") to expel the drug 22 from the drug storage container 20 through the delivery member 16 into the patient. In the present embodiment, the drive mechanism 30 is configured to store mechanical potential energy; however, alternative embodiments of the drive mechanism 30 may be configured differently, for example, with the drive mechanism 30 storing electrical or chemical potential energy. Generally, upon activation of the drive mechanism 30, the drive mechanism 30 may convert the potential energy into kinetic energy for moving the plunger 26. The drive mechanism 30 may include a plunger biasing member 50, a hollow rod 46 for supporting the plunger biasing member 50, a plunger biasing member seat 38, the releaser member 52, a plunger rod guide 60, an extender biasing member 35, and a guard extension 37. The plunger biasing member 50

may include a spring, such as a compression spring (e.g., a helical compression spring) which is initially retained in an energized state. In the energized state, the plunger biasing member 50 may be compressed such that its axial length is shorter than it would be in a natural or de-energized state. When released, the plunger biasing member 50 may try to expand to its natural axial length, and as a consequence, exert a biasing force pushing the plunger 26 in the distal direction. In other embodiments, the plunger biasing member 50 may include a torsion spring, which is initially retained in an energized state. When released, the plunger biasing member 50 may rotate, and as a consequence, cause the plunger 26 to rotate while translating in the distal direction.

**[0037]** As shown in Fig. 2, the drug delivery device 10 may include a housing 12, which may include two separate and interconnected structures: a rear end cap 23 (e.g., a rear cap) at the proximal end of the drug delivery device 10 and a tubular housing 25 extending substantially completely along the length of the drug delivery device 10 and defining the opening 14.

Additionally or alternatively, the housing 12 may include fewer or more components. The tubular housing 25 may have a hollow and generally cylindrical or tubular shape, and the rear end cap 23 may have a generally hemispherical shape or a hollow cylindrical shape with an open end and a closed off end. In some embodiments, the rear end cap 23 and the tubular housing 25, and any components to be positioned therein, may be assembled together to define different sub-assemblies, such as the drive mechanism 30. In some embodiments, the different sub-assemblies are assembled independently of each other and then later combined with one another, as well as with the drug storage container 20, to form the fully-assembled drug delivery device 10. In certain such embodiments, some or all of the foregoing phases of assembly may occur in different manufacturing facilities or environments. In alternative embodiments, the housing 12 may be constructed in one piece, such that the housing 12 is defined by a single, monolithic structure that integrates a rear cap 23 and tubular housing 25 in a single component.

**[0038]** The drug storage container 20 is disposed within an interior space of the housing 12 and is configured to contain a drug 22. The drug storage container 20 may be pre-filled and shipped, e.g., by a manufacturer, to a location where the drug storage container 20 is combined with a remainder of the drug delivery device 10. For example, the drug 22 may be distributed and/or provided to patients in more than one use case, such as a as a pre-filled syringe or as an autoinjector including a pre-filled syringe. By utilizing the same or similar syringe components in either case, at least some of above steps such as filling, labeling, packaging, shipping, and distribution may be streamlined or simplified for two different use cases. As another example, in the event that multiple use cases utilize some or all of the same syringe components, some regulatory pathways to marketing and/or distributing the drug may be streamlined and/or simplified for at least one of the multiple use cases.

**[0039]** The housing 12 may be pre-loaded with the drug storage container 20, e.g., by a manufacturer, or alternatively, loaded with the drug storage container 20 by a user prior to use

of the drug delivery device 10. The drug storage container 20 may include a barrel having a rigid wall defining an internal bore or reservoir. The wall may be made of glass or plastic. A stopper 24 may be moveably disposed in the barrel of the drug storage container 20 such that it can move in a distal direction along the longitudinal axis A between proximal end and a distal end of the drug storage container 20. The stopper 24 may be constructed of rubber or any other suitable material. The stopper 24 may slidably and sealingly contact an interior surface 15 of the wall of the drug storage container 20 such that the drug 22 is prevented or inhibited from leaking past the stopper 24 when the stopper 24 is in motion. Distal movement of the stopper 24 expels the drug 22 from the reservoir of the drug storage container 20 into the delivery member 16. The proximal end of the drug storage container 20 may be open to allow a plunger 26 to extend into the drug storage container 20 and push the stopper 24 in the distal direction. In the present embodiment, the plunger 26 and the stopper 24 are initially spaced from each other by a gap 18 (Fig. 2). Upon activation of a drive mechanism 30, the plunger 26 moves in the distal direction to close the gap and comes into contact with the stopper 24. Subsequent distal movement of the plunger 26 drives the stopper 24 in the distal direction to expel the drug 22 from the drug storage container 20. In alternative embodiments, the stopper 24 and the plunger 26 may initially be in contact with one another or coupled to one another, e.g., via a threaded coupling, such that they move together jointly from the start of movement of the plunger 26. Once the stopper 24 is in motion, it may continue to move in the distal direction until it contacts a proximally-facing portion of the interior surface 15 of the wall of the drug storage container 20. This position of the stopper 24 may be referred to as the end-of-dose or end-of-delivery position, and may correspond to when delivery of the drug 22 to the patient is complete or substantially complete.

**[0040]** In some embodiments, a volume of the drug 22 included in the reservoir of the drug storage container 20 may be equal to 1 mL, or equal to approximately (e.g.,  $\pm 10\%$ ) 1 mL, or equal to 2.5 mL, or equal to approximately (e.g.,  $\pm 10\%$ ) 2.5 mL, or equal to 3 mL, or equal to approximately (e.g.,  $\pm 10\%$ ) 3 mL, or less than or equal to approximately (e.g.,  $\pm 10\%$ ) 1 mL, or less than or equal to approximately (e.g.,  $\pm 10\%$ ) 2 mL, or less than or equal to approximately (e.g.,  $\pm 10\%$ ) 3 mL, or less than or equal to approximately (e.g.,  $\pm 10\%$ ) 4 mL, or less than approximately (e.g.,  $\pm 10\%$ ) 5 mL, or less than or equal to approximately (e.g.,  $\pm 10\%$ ) 10 mL, or within a range between approximately (e.g.,  $\pm 10\%$ ) 1 – 10 mL, or within a range between approximately (e.g.,  $\pm 10\%$ ) 1 – 5 mL, or within a range between approximately (e.g.,  $\pm 10\%$ ) 1 – 4 mL, or within a range between approximately (e.g.,  $\pm 10\%$ ) 1 – 3 mL, or within a range between approximately (e.g.,  $\pm 10\%$ ) 1 - 2.5 mL.

**[0041]** The delivery member 16 is connected or operable to be connected in fluid communication with the reservoir of the drug storage container 20. For example, the delivery member 16 may be positioned at a distal end of the barrel of the drug storage container 20. A distal end of the delivery member 16 may define the insertion end 28 of the delivery member 16.

The insertion end 28 may include a sharpened tip of other pointed geometry allowing the insertion end 28 to pierce the patient's skin 5 (Figs. 1C and 1D) and subcutaneous tissue during insertion of the delivery member 16. The delivery member 16 may be hollow and have an interior passageway. One or more openings may be formed in the insertion end 28 to allow drug to flow out of the delivery member 16 into the patient.

**[0042]** In one embodiment, the drug storage container 20 may be a pre-filled syringe and has a staked, hollow metal needle for the delivery member 16. Here, the needle is fixed relative to the wall of the drug storage container 20 and may be in permanent fluid communication with the reservoir of the drug storage container 20. In other embodiments, the needle may be coupled to the drug storage container 20 via a Luer Lock or other suitable connection. In yet other embodiments, the drug storage container 20 may be a needle-less cartridge, and, as such, initially may not be in fluid communication with the delivery member 16. In such embodiments, the drug storage container 20 may move toward a proximal end of the delivery member 16, or vice versa, during operation of the drug delivery device 10 such that the proximal end of the delivery member 16 penetrates through a septum covering an opening in the drug storage container 20 thereby establishing fluid communication between the reservoir of the drug storage container 20 and the delivery member 16.

**[0043]** The drug storage container 20 may include a body portion 20g with a distal end 20e and a proximal end 20f. The drug storage container 20 may be fixed relative to the housing 12 such that the drug storage container 20 does not move relative to the housing 12 once installed in the housing 12. As such, the insertion end 28 of the delivery member 16 extends permanently through the opening 14 in the housing 12 in the pre-injection, injection, and post-injection states. For example, as shown in Fig. 2, the delivery member 16 extends beyond a distal end of the housing 12 that defines the opening 14. However, in some configurations, such as the storage configuration shown in Fig. 2, the delivery member 16 is covered / protected by the sterile barrier 21 and a guard member 32 that surrounds the delivery member 16 and protects against or reduces the likelihood of unintended or premature needle stick, as will be discussed in more detail below. The term "body portion" of the drug storage container 20 as used herein is the generally cylindrical portion of the drug storage container 20.

**[0044]** As shown in Fig. 2, the plunger biasing member 50 may be disposed at least partially within the plunger 26, and may have a distal end abutting against a proximally facing inner surface of the plunger 26 and/or may be fixedly attached to an inner surface of the plunger 26. So that the plunger biasing member 50 may be received within the plunger 26, an outer diameter or other dimension of the plunger biasing member 50 may be equal to or less than an inner diameter of the top ring 45 and/or equal to or less than an inner diameter of the hollow rod 46. In some embodiments, the distal end of the plunger biasing member 50 may abut against a proximally facing inner surface of the base 47 of the plunger 26. Furthermore, a proximal end of the plunger biasing member 50 may abut against a distally facing surface 38a of the plunger

biasing member seat 38. The plunger biasing member seat 38 may be fixedly attached to the rear housing 27 such that the plunger biasing member seat 38 provides a stationary surface for the plunger biasing member 50 to push off of. So configured, the plunger biasing member 50, when released from the energized state, may expand in length with distal end of the plunger biasing member 50 moving in the distal direction away from the stationary proximal end of the plunger biasing member 50. This motion may push the plunger 26 in the distal direction, which, in turn, may push the stopper 24 in the distal direction to expel the drug 22 from the drug storage container 20 into the delivery member 16 and thereafter into the patient.

**[0045]** The plunger rod guide 60 may be fixedly attached to the rear housing 27 such that the plunger rod guide 60 is immovable relative to the rear housing 27. The plunger rod guide 60 may have a hollow and generally cylindrical or tubular shape, and may be centered about the longitudinal axis A. An outer diameter or other outer dimension of a proximal end of the plunger rod guide 60 may be larger than an outer diameter or other outer dimension of a distal end of the plunger rod guide 60. At least a portion of the distal end of the plunger rod guide 60 may be positioned radially between the plunger 26 and the releaser member 52. As such, the plunger 26 may be disposed at least partially within the distal end of the plunger rod guide 60, and the distal end of the plunger rod guide 60 may be disposed at least partially within the releaser member 52, as illustrated in Fig. 2.

**[0046]** The releaser member 52 may have a hollow and generally cylindrical or tubular shape, and may be centered about the longitudinal axis A. As illustrated in Fig. 2, the releaser member 52 may be positioned in the radial direction between the distal end of the plunger rod guide 60 and a proximal end of the guard extension 37. Furthermore, the releaser member 52 may be arranged radially inwardly of the guard biasing member 35. Generally, the releaser member 52 is configured to operably couple the guard member 32 and the plunger 26 in an activation sequence and to generate an audible signal indicating the end of drug delivery.

**[0047]** The releaser member 52 may be configured to rotate relative to the housing 12 and/or translate linearly relative to the housing 12, depending on the stage of operation of the drug delivery device 10. Initial rotation of the releaser member 52 associated with activation may be powered by the plunger biasing member 50 and/or the guard biasing member 35; whereas later rotation of the releaser member 52 associated with generation of the end-of-dose signal may be powered solely by the guard biasing member 35. Any linear translation of the releaser member 52 without rotation may be powered solely by the guard biasing member 35. In some embodiments, the releaser member 52 may translate linearly only in the proximal direction; however, alternative embodiments may permit linear translation of the releaser member 52 in both the proximal and distal directions.

**[0048]** As discussed above, the drug delivery device 10 may further include a guard mechanism for preventing contact with the insertion end 28 of the delivery member 16 when the drug delivery device 10 is not being used to administer an injection. The guard mechanism may

include a guard member 32 moveably disposed at the distal end of the housing 12 adjacent to the opening 14. The guard member 32 may have a hollow and generally cylindrical or tubular shape centered about the longitudinal axis A. The guard member 32 may generally include a cylindrical portion 32a, a distal end 32c, and a proximal end 32d. The cylindrical portion 32a may be at least partially and/or selectively received within the housing 12. For example, the guard member 32 may be configured to move relative to the housing 12 such that portions of the guard member 32 are received within the housing 12 in some stages / states and are extending from the housing 12 in other stages / states.

**[0049]** The guard member 32 may be configured to move relative to the housing 12 between an extended position wherein at least a portion of the cylindrical portion 32a of the guard member 32 extends through the opening 14 in the housing 12 and a retracted position wherein a shorter length of the cylindrical portion 32a or no part of the cylindrical portion 32a extends through the opening 14 in the housing 12. In other words, in the extended position, a length X of the cylindrical portion 32a extends through the opening 14 in the housing 12 and in the retracted position, a length Y of the cylindrical portion 32a extends through the opening 14 in the housing 12, wherein X is a value greater than Y. The length X may be any suitable number such as 10 mm, 8 mm, 6 mm, 4mm, 2 mm, 1 mm, or another value. The length Y may be any suitable number that is less than X, such as 3 mm, 2 mm, 1 mm, 0.5 mm, 0 mm, or another value. Figs. 1C and 1D illustrate an exemplary pre-injection configuration (Fig. 1C) where the guard member 32 is in an extended position 32e and the length of the exposed portion X of the guard member 32 may be approximately 5 mm to 11 mm and an injection configuration (Fig. 1D) where the guard member 32 is in a retracted position 32f and the length of the exposed portion Y of the guard member 32 is approximately 0 mm to 2 mm (such that the distal end 32c of the guard member 32 is flush with the opening 14 of the housing 12). In one embodiment, the distance Y is greater than 0 (e.g. 1 mm) to help ensure the device 10 is able to be activated before the guard member is flush with the housing 12.

**[0050]** During operation of the device, a user may cause the guard member 32 to translate (with respect to the housing 12) in the proximal direction by pressing the guard member 32 against the injection site. In doing so, the guard member 32 will move towards the guard extension 37 and close the gap 37g therebetween (Fig. 2). Once the gap 37g is eliminated, the guard member 32 and the guard extension 37 move jointly in the proximal direction until, for example, the guard member 32 reaches the retracted position 32f. When the injection is complete and the drug delivery device 10 is lifted off of the injection site, the extender biasing member 35 may urge the guard extension 37 so that the guard extension 37 and the guard member 32 move jointly in the distal direction. This motion (and/or a biasing force from lock ring biasing member 51) returns the guard member 32 to the extended position 32e, which has the effect of covering the insertion end 28 of the delivery member 16.

**[0051]** Often times, however, the user may not know when to stop applying force against the guard member 32 and pressing the guard member 32 against the injection site. Additionally, the user may not know when to maintain the input force exerted against the guard member 32 to ensure that insertion end 28 of the delivery member 16 is properly and sufficiently inserted in the injection site throughout the duration of the injection. This, in turn, can make it difficult for the user to self-administer a drug and can increase the likelihood of improper dose administration. As the demand grows for drug delivery devices with greater ease of use and safety, it may be desirable to provide the drug delivery device 10 with additional features that indicate to the user when to hold an input force exerted against the guard member 32 to ensure proper dose administration.

**[0052]** Figs. 3A-3D, for example, illustrate different views of a drug delivery device 100, in accordance with various embodiments of the present disclosure. The drug delivery device 100 may comprise the same components that make up the drug delivery device 10. By way of example, the drug delivery device 100 may comprise the drive mechanism 30, the drug storage container 20, the delivery member 16, the releaser member 52, and other components discussed above with respect to the drug delivery device 10.

**[0053]** As illustrated in Figs. 3A-3D, the drug delivery device 100 includes an outer casing or housing 112. Like the housing 12, the housing 112 may have a generally elongate shape, such as a cylindrical shape, and extend along a longitudinal axis A between a proximal end 112e and a distal end 112f. An opening 114 (Figs. 3C and 3D) may be formed in the distal end 112f to permit an insertion end 128 of a delivery member 116 to extend outside of the housing 112 in certain configurations. A transparent or semi-transparent inspection window 117 may be positioned in a wall of the housing 112 to permit a user to view component(s) inside the drug delivery device 100, including a drug storage container 120 (similar to the drug storage container 20). Although not shown, a removable cap like the removable cap 19 may cover the opening 114 prior to use of the drug delivery device 100. The drug delivery device 100 may also comprise a rear end cap 123 (also referred to as "rear cap") at the proximal end 112e of the drug delivery device 100.

**[0054]** The drug delivery device 100 may further include a guard mechanism for preventing contact with the insertion end 128 of the delivery member 116 when the drug delivery device 100 is not being used to administer an injection. The guard mechanism may include a guard member 132 moveably disposed at or near the distal end 112f of the housing 112 adjacent to an opening 140 (shown in Fig. 3C). As discussed in more detail below, the guard member 132 may be moveable relative to the housing 112 between an extended position (Figs. 3A and 3C) and a retracted position (Figs. 3B and 3D). When the guard member 132 is in the extended position (Figs. 3A and 3C), the insertion end 128 of the delivery member 116 may be surrounded by the guard member 132 such that the insertion end 128 of the delivery member 116 is not visible to the user. When the guard member 132 is in the retracted position (Figs. 3B and 3D), the

insertion end 128 of the delivery member 116 may be at least partially exposed such that it is visible to the user operating the drug delivery device 100.

**[0055]** Similar to the guard member 32, the guard member 132 may be hollow and generally tubular-shaped. However, unlike the guard member 32 of the drug delivery device 100, the guard member 132 of the drug delivery device 100 may include a first annular portion 132a and a second annular portion 132b disposed at a distal end of the first annular portion 132a. The first annular portion 132a may be hollow and generally tubular-shaped and may be a cylindrical portion centered about the longitudinal axis A. The second annular portion 132b may be disposed at a distal end of the first annular portion 132a and may also be a generally cylindrical portion centered about the longitudinal axis A. In some embodiments, the second annular portion 132b may be coupled to the first annular portion 132a. For example, the second annular portion 132b may be glued to the first annular portion 132a, or coupled to the first annular portion 132a via a snap-fit configuration or via other known mechanisms for coupling the second annular portion 132b to the first annular portion 132a. In other embodiments, the first annular portion 132a and the second annular portion 132b may be formed integrally and may define a single, monolithic structure.

**[0056]** As shown in Figs. 3A-3D, the second annular portion 132b may have an outer diameter that is greater than an outer diameter of the first annular portion 132b. In some embodiments, the outer diameter of the second annular portion 132b may be substantially equal to or at least similar to the outer diameter of the distal end 112f of the housing 112. Accordingly, when the guard member 132 is in the retracted position (Figs. 3B and 3D), the outer diameter of the second annular portion 132b may match the outer diameter of at least the distal end 112f of the housing 112 such that the second annular portion 132b sits flush with the distal end 112f of the housing 112.. The outer diameter of the first annular portion 132a may be smaller than the outer diameter of the second annular portion 132b and at least the distal end 112f of the housing 112 such that the first annular portion 132a can slide in and out of the housing 112 between the extended position and the retracted position.

**[0057]** As indicated above, the guard member 132 may be configured to move relative to the housing 112 between the extended position wherein at least a portion of the first annular portion 132a extends through an opening 140 in the housing 112 and the retracted position wherein a shorter length or no part of the first annular portion 132a extends through the opening 140 of the housing 112. In other words, in the extended position, a length X (shown in Fig. 3C) of the first annular portion 132a may extend through the opening 140 of the housing 112 and, in the retracted position, a length Y (shown in Fig. 3D) of the first annular portion 132a may extend through the opening 140, wherein X is a value greater than Y. The length X may be any suitable number such as 10 mm, 8 mm, 6 mm, 4 mm, 2 mm, 1 mm, or another value. The length Y may be any suitable number that is less than X, such as 3 mm, 2 mm, 1 mm, 0.5 mm, 0 mm, or another value.

**[0058]** When the guard member 132 is in the extended position (Figs. 3A and 3C), the second annular portion 132b may be positioned at a first distance away from a distal end 112f of the housing 112 such that the first annular portion 132a and the second annular portion 132b may cover the insertion end 128 of the delivery member 116. The first distance may be equal to the length X of the first annular portion 132a that extends through the opening 140 of the housing 112. When the guard member 132 is in the retracted position (Figs. 3B and 3D), the first annular portion 132a may move in the proximal direction and at least a portion of the first annular portion 132a may slide into the distal end 112f of the housing 112, and the second annular portion 132b may also move in the proximal direction toward the proximal end 112e of the housing 112. Accordingly, when the guard member 132 is in the retracted position, the second annular portion 132b of the guard member 132 may be positioned a second distance (smaller than the first distance) from the distal end 112f of the housing 112 and thereby at least partially expose the insertion end 128 of the delivery member 116. The second distance may be equal to the length Y of the first annular portion 132a that extends through the opening 140 of the housing 112.

**[0059]** The guard member 132 may also be configured to move in the opposite, distal direction, namely from the retracted position to the extended position. During the injection process, the guard member 132 may remain stationary with respect to the user's skin while the housing 112 and several components disposed therein, such as the drive mechanism and the delivery member 116, are moving with respect to the guard member 132 and the skin. In some embodiments, the guard member 132 may be rotationally fixed or rotationally restricted relative to the housing 112. Accordingly, although the guard member 132 may be able to translate linearly relative to the housing 112, the guard member 132 may be substantially or completely prevented from rotating relative to the housing 112. By way of example, the first annular portion 132a of the guard member 132 may include a protrusion 172 extending therefrom that aligns with a corresponding feature on the inner surface of the housing 112, such as a slot, a ridge, or another component that cooperates with the protrusion 172 to substantially or completely prevent rotation of the guard member 132. In some embodiments, the first annular portion 132a may comprise a plurality of protrusions 172, and the inner surface of the housing 112 may comprise a plurality of corresponding features.

**[0060]** As discussed above, the first annular portion 132a of the guard member 132 may be at least partially defined by an annular side wall, and at least a portion of the annular side wall of the first annular portion 132a may be configured to slide within the housing 112 between the extended position and the retracted position. Referring to Figs. 3A-3D, the second annular portion 132b of the guard member 132 may be defined by an annular side wall 151, a bottom wall 152 configured to contact a skin of the user during operation of the drug delivery device 100, and a top wall 150 opposite the bottom wall 152. In some embodiments, as illustrated in Figs. 3A-3D, the top wall 150 of the second annular portion 132b may include a first stepped

surface, and the distal end 112f of the housing 112 may also include a second stepped surface that is complementary to the first stepped surface. Accordingly, when the guard member 132 moves from the extended position to the retracted position, the first stepped surface of the top wall 150 of the second annular portion 132b may match the second stepped surface of the distal end 112f of the housing 112 (as shown in Figs. 3B and 3D). In other embodiments, when the guard member 132 is in the retracted position, the first stepped surface of the top wall 150 of the second annular portion 132b may be flush with the second stepped surface of the distal end 112f of the housing 112.

**[0061]** The complementary stepped surfaces of the top wall 150 of the second annular portion 132b of the guard member 132 and the distal end 112f of the housing 112 may provide a visual indication or feedback to the user of when the user should: (a) stop applying force against the guard member 132 and pressing the bottom wall 152 against the injection site, and (b) maintain the input force exerted against the guard member 132 to ensure that insertion end 128 of the delivery member 116 is properly and sufficiently inserted in the injection site throughout the duration of the injection. In particular, the user may be instructed to exert a force against the guard member 132 by pressing the bottom wall 152 of the second annular portion 132b against the skin of the user until a consistent length 170 of the first annular portion 132a (shown in dotted lines in Fig. 3B) can be seen around the guard member 132. This, in turn, can ensure proper dose administration by the user. Additionally, or alternatively, the drug delivery device 100 may be configured to provide a tactile and/or audible feedback to the user to notify when the user should (a) stop applying force against the guard member 132 and pressing the bottom wall 152 against the injection site, and (b) maintain the input force exerted against the guard member 132 to ensure that insertion end 128 of the delivery member 116 is properly and sufficiently inserted in the injection site throughout the duration of the injection.

**[0062]** Referring back to Fig. 2, like the drug delivery device 10, the drug delivery device 100 may also comprise an extender biasing member 35 and a guard extension 37. The guard extension 37 may be positioned proximal to the guard member 132, and the extender biasing member 35 may be positioned proximal to the guard extension 37. The guard extension 37 may have a hollow and generally cylindrical or tubular shape centered about the longitudinal axis A. The guard extension 37 may be a separate structure from the guard member 132. In other embodiments, the guard extension 37 may be integrally formed with the guard member 132 to define a single, monolithic structure. The guard extension 37 may be rotationally fixed relative to the housing 112. To achieve this effect, in some embodiments, the guard extension 37 may cooperate with a plunger guide, such as plunger rod guide 60, to restrict or prevent rotation.

**[0063]** In some embodiments, the extender biasing member 35 may be positioned between and in contact with the guard extension 37 and a releaser member, such as releaser member 52. The extender biasing member 35 may be configured to bias or urge the guard extension 37 in the distal direction and/or bias or urge the releaser member 52 in the proximal direction. In the

device 100 shown in Figs. 3A and 3C, which is in the pre-delivery or extended position, the extender biasing member 35 may be initially in an energized state (e.g., compressed). In other words, the extender biasing member 35 may exert a distal direction (downward) biasing force on the guard extension 37 and a proximal direction (upward) biasing force on the releaser member 52. During operation of the device, a user may cause the guard member 132 to translate with respect to the housing 112 in the proximal direction by pressing the guard member 132, and particularly the bottom wall 152 of the second annular portion 132b), against the injection site. In doing so, the guard member 132 may move towards the guard extension 37 and close the gap 37g (shown in Fig. 2) therebetween. Once the gap 37g is eliminated, the guard member 132 and the guard extension 37 may move jointly in the proximal direction until, for example, the guard member 132 reaches the retracted position (Figs. 3B and 3D). When the injection is complete and the drug delivery device 100 is lifted off of the injection site, the extender biasing member 35 may urge the guard extension 37 so that the guard extension 37 and the guard member 132 move jointly in the distal direction. This motion may return the guard member 132 to the extended position, and the guard member 132 may cover the insertion end 128 of the delivery member 116 to prevent inadvertent injection of the delivery member 116 into the user's skin after dose delivery. In some embodiments, the extender biasing member 35 may include a compression spring (e.g., a helical compression spring).

**[0064]** After the drug delivery is complete and the guard member 132 has been re-deployed to the extended position, it may be desirable to lock the guard member 132 in the extended position to prevent subsequent user contact with the insertion end 128 of the delivery member 116 and/or to prevent re-use of the drug delivery device 100. In some embodiments, the drug delivery device 100 may include a lock ring, such as lock ring 40, configured to selectively rotate between a first rotational position and a second rotational position, depending on the axial position of the guard member 132, in order to lock the guard member 132 in the extended position once the guard member 132 has moved from the retracted position back to the extended position. In some embodiments, the lock ring may be centered and may rotate about the longitudinal axis A. A proximal end of the lock ring may be in contact with a portion of the housing 112 and a distal end of the lock ring may be disposed at least partially within the guard member 132.

**[0065]** In some embodiments, the drug delivery device 100 may also include a lock ring biasing member, such as lock ring biasing member 51. The lock ring biasing member may be positioned in the axial direction between a distally facing surface of the lock ring and a proximally facing surface of the bottom wall 152 of the second annular portion 132b of the guard member 132. In some embodiments, the lock ring biasing member may be positioned within the first annular portion 132a of the guard member 132. The lock ring biasing member may be a compression spring and may be configured to exert a biasing force on the guard member 132 to

urge the guard member 132 toward the extended position. The lock ring biasing member may also bias the lock ring and the guard member away from each other.

**[0066]** In some embodiments, the drug delivery device 100 may comprise a plunger guide, such as plunger rod guide 60, fixed relative to the housing 112. A plunger, such as plunger 26, may be disposed at least partially within the plunger guide. As discussed above, a releaser member, such as releaser member 52, may be operably coupled to the plunger and may be configured to selectively rotate relative to the housing. The plunger and the plunger guide may be disposed at least partially within the releaser member, and the guard member 132 may be operably coupled to the releaser member. When the guard member 132 is in the extended position, the releaser member may be prevented from rotating in at least one rotational direction, and the releaser member may be allowed to rotate in the at least one rotational direction when the guard member 132 is in the retracted position. In particular, when the guard member 132 moves from the extended position to the retracted position, this movement of the guard member 132 may allow the releaser member and the plunger to rotate jointly from a first rotational position toward a second rotational position under a biasing force exerted by a biasing member, such as a spring.

**[0067]** Having described the general configuration of the drug delivery device 100, a method of using the drug delivery device 100 to perform an injection will now be described. As a preliminary step, the user may remove a removable cap, such as removable cap 19, from the distal end 112f of the housing 112. This may uncover the insertion end 128 of the delivery member 116. Nevertheless, the insertion end 128 may remain surrounded by the guard member 132 because the guard member 132 is arranged in the extended position. Next, the user may position the drug delivery device 110 over the injection site, grip the housing 112, and push the bottom wall 152 of the second annular portion 132b of the guard member 132 against the injection site while gripping the housing 112. The user may push the bottom wall 152 against the injection site until a consistent line 170 (shown in Figs. 3B and 3D) can be seen around the first annular portion 132a of the guard member 132. At this point, the user may stop pushing the bottom wall 152 further and may hold the force applied against the injection site until the drug delivery is complete.

**[0068]** The force applied by the user will overcome the biasing force of the extender biasing member and the biasing force of the lock ring biasing member, thereby causing the guard member 132 to retract into the opening 140 moving from the extended position to the retracted position in the proximal direction. The delivery member 116 remains stationary relative to the housing 112 during the retracting movement of the guard member 132. Because the delivery member 116 remains stationary, the insertion end 128 of the delivery member 116 is caused to extend through the opening 114 in the bottom wall 152 of the second annular portion 132b of the guard member 132, thereby piercing the user's skin at the injection site and penetrating into the user's subcutaneous tissue.

**[0069]** In the pre-injection state, the plunger and the releaser member may be arranged in a respective initial rotational position. The plunger biasing member may also be in an energized, compressed state. When the guard member 132 moves into the retracted position, this causes axial movement of the guard extension, which unlocks the releaser member. Once the releaser member is unlocked, the plunger and the plunger biasing member urge the releaser member to rotate clockwise and permit axial movement of the plunger in the distal direction (downward toward the distal end 112f of the housing 112). The plunger then urges the stopper in the distal direction, thereby urging the drug from the drug product container 120 and out of the delivery member 116. Once the drug delivery is complete, the user may then left the drug delivery device 100 off of the injection site. With nothing to resist it, the extender biasing member may push the guard member 132 from the retracted position back to the extended position to cover the insertion end 128 of the delivery member 116. This movement of the guard member 132 may also cause the lock ring to rotate from a first rotational position to a second rotational position to lock the guard member 132 in the extended position and prevent subsequent retraction of the guard member 132.

**[0070]** Turning now to Figs. 4A-4B, another drug delivery device 200, in accordance with various embodiments of the present disclosure, is provided. The drug delivery device 200 may be similar to the drug delivery device 100 of Figs. 3A-3D. For example, like the drug delivery device 100, the drug delivery device 200 includes an outer casing or housing 212. The housing 212 may have a generally elongate shape, such as a cylindrical shape, and extend along a longitudinal axis A between a proximal end 212e and a distal end 212f. An opening 214 may be formed in the distal end 212f to permit an insertion end 228 of a delivery member 216 to extend outside of the housing 212 in certain configurations. A transparent or semi-transparent inspection window 217 may be positioned in a wall of the housing 212 to permit a user to view component(s) inside the drug delivery device 200, like a drug storage container similar to drug storage container 120. Although not shown, a removable cap like the removable cap 19 may cover the opening 214 prior to use of the drug delivery device 200. The drug delivery device 200 may also comprise a rear end cap 223 at the proximal end 212e of the drug delivery device 200.

**[0071]** The drug delivery device 200 may further include a guard mechanism for preventing contact with the insertion end 228 of the delivery member 216 when the drug delivery device 200 is not being used to administer an injection. The guard mechanism may include a guard member 232 moveably disposed at or near the distal end 212f of the housing 212 adjacent to an opening 240 (shown in Fig. 4A). As discussed in more detail below, the guard member 232 may be moveable relative to the housing 212 between an extended position (Fig. 4A) and a retracted position (Fig. 4B). When the guard member 232 is in the extended position (Fig. 4A), the insertion end 228 of the delivery member 216 may be surrounded by the guard member 232 such that the insertion end 228 is not visible to the user. When the guard member 232 is in the

retracted position (Fig. 4B), the insertion end 228 may be at least partially exposed such that it is visible to the user and such that it can pierce through the user's skin at the injection site.

**[0072]** The guard member 232 may be hollow and generally tubular-shaped. The guard member 232 may include a first annular portion 232a and a second annular portion 232b disposed at a distal end of the first annular portion 232a. The first annular portion 232a may be hollow and generally tubular-shaped and may be a cylindrical portion centered about the longitudinal axis A. The second annular portion 232b may be disposed at a distal end of the first annular portion 232a and may also be a generally cylindrical portion centered about the longitudinal axis A. In some embodiments, the second annular portion 232b may be coupled to the first annular portion 232a. For example, the second annular portion 232b may be glued to the first annular portion 232a, or coupled to the first annular portion 232a via a snap-fit configuration or via other known mechanisms for coupling the second annular portion 232b to the first annular portion 232a. In other embodiments, the first annular portion 232a and the second annular portion 232b may be formed integrally and may define a single, monolithic structure.

**[0073]** As shown in Figs. 4A-4B, the second annular portion 232b may have an outer diameter that is greater than an outer diameter of the first annular portion 232b. In some embodiments, the outer diameter of the second annular portion 232b may be smaller than an outer diameter of the housing 212 proximate the distal end 212f such that when the guard member 232 is in the retracted position, at least a portion of the second annular portion 232b may slide through an opening in the distal end 212f and within the housing 212. The outer diameter of the first annular portion 232a may be smaller than the outer diameter of the second annular portion 232b and at least the distal end 212f of the housing 212 such that the first annular portion 232a can slide in and out of the housing 212 through an opening (such as opening 240) at the distal end 212f of the housing 212 between the extended position and the retracted position. In other embodiments, the outer diameter of the second annular portion 232b may be substantially equal to or at least similar to the outer diameter of the distal end 212f of the housing 212. In this configuration, when the guard member 232 is in the retracted position, the outer diameter of the second annular portion 232b may match the outer diameter of at least the distal end 212f of the housing 212 such that the second annular portion 232b sits flush with the distal end 212f of the housing 212.

**[0074]** Like the guard member 132, the guard member 232 may be configured to move relative to the housing 212 between the extended position wherein at least a portion of the first annular portion 232a extends through an opening 240 in the housing 212 and the retracted position wherein a shorter length or no part of the first annular portion 232a extends through the opening 240 of the housing 212. In other words, in the extended position, a length X of the first annular portion 232a may extend through the opening 240 of the housing 212 and, in the retracted position, a length Y of the first annular portion 232a may extend through the opening

240, wherein X is a value greater than Y. The length X may be any suitable number such as 10 mm, 8 mm, 6 mm, 4 mm, 2 mm, 1 mm, or another value. The length Y may be any suitable number that is less than X, such as 3 mm, 2 mm, 1 mm, 0.5 mm, 0 mm, or another value.

**[0075]** When the guard member 232 is in the extended position (Fig. 4A), the second annular portion 232b may be positioned at a first distance away from a distal end 212f of the housing 212 such that the first annular portion 232a and the second annular portion 232b may cover the insertion end 228 of the delivery member 216. The first distance may be equal to the length X of the first annular portion 232a that extends through the opening 240 of the housing 212. When the guard member 232 is in the retracted position (Fig. 4B), the first annular portion 232a may move in the proximal direction and at least a portion of the first annular portion 232a may slide into the distal end 212f of the housing 212, and the second annular portion 232b may also move in the proximal direction toward the proximal end 212e of the housing 212. Accordingly, when the guard member 232 is in the retracted position, the second annular portion 232b of the guard member 232 may be positioned a second distance (smaller than the first distance) from the distal end 212f of the housing 212 and thereby at least partially expose the insertion end 228 of the delivery member 216. The second distance may be equal to the length Y of the first annular portion 232a that extends through the opening 240 of the housing 212.

**[0076]** In some embodiments, when the guard member 232 is in the retracted position, at least a portion of the second annular portion 232b may slide into the distal end 212f of the housing 212 via the opening 240 such that no part of the first annular portion 232a is visible. In this case, when the guard member 232 is in the retracted position, the first annular portion 232a is completely disposed within the housing 212 such that no part of the first annular portion 232a is visible, and at least a portion of the second annular portion 232b is disposed within the housing 212. In yet another embodiment, when the guard member 232 is in the retracted position, the second annular portion 232b may sit flush with the distal end 212f of the housing 212. In this configuration, the first annular portion 232a is completely disposed within the housing 212 such that no part of the first annular portion 232a is visible, and the second annular portion 232b is disposed 0 mm away from the distal end 212f of the housing 212 while no part of the second annular portion 232b is disposed inside the housing 212 (i.e., in contact with the distal end 212f of the housing 212).

**[0077]** As discussed above, the first annular portion 232a of the guard member 232 may be at least partially defined by an annular side wall, and at least a portion of the annular side wall of the first annular portion 232a may be configured to slide within the housing 212 between the extended position and the retracted position. The second annular portion 232b may be defined by an annular side wall 251, a bottom wall 252 configured to contact a skin of the user during operation of the drug delivery device 200, and a top wall 250 opposite the bottom wall 252. In some embodiments, as illustrated in Figs. 4A-4B, the top wall 250 of the second annular portion 232b may include a first stepped surface, and the distal end 212f of the housing 212 may also

include a second stepped surface that is complementary to the first stepped surface.

Accordingly, when the guard member 232 moves from the extended position to the retracted position, the first stepped surface of the top wall 250 of the second annular portion 232b may match the second stepped surface of the distal end 212f of the housing 212 (as shown in Fig. 4B) such that the first stepped surface of the top wall 250 may be flush with the second stepped surface of the distal end 212f of the housing 212.

**[0078]** The complementary stepped surfaces of the top wall 250 of the second annular portion 232b of the guard member 232 and the distal end 212f of the housing 212 may provide a visual indication or feedback to the user of when the user should: (a) stop applying force against the guard member 232 and pressing the bottom wall 252 against the injection site, and (b) maintain the input force exerted against the guard member 232 to ensure that insertion end 228 of the delivery member 216 is properly and sufficiently inserted in the injection site throughout the duration of the injection. In particular, the user may be instructed to exert a force against the guard member 232 by pressing the bottom wall 252 of the second annular portion 232b against the skin of the user until no part of the first annular portion 232a of the guard member 232 is visible. This, in turn, can ensure proper dose administration by the user. Additionally, the second annular portion 232b of the guard member 232 and the housing 212 may each comprise an indicator 280 to indicate to the user when the user should: (a) stop applying force against the guard member 232 and pressing the bottom wall 252 against the injection site, and (b) maintain the input force exerted against the guard member 232 to ensure that insertion end 228 of the delivery member 216 is properly and sufficiently inserted in the injection site throughout the duration of the injection. The indicator 280 may comprise an arrow, as shown in Figs. 4A-4B, or any other geometric shape that can be matched to each other. For example, as shown in Fig. 5, the second annular portion 232b of the guard member 232 and the distal end 212f of the housing 212 may each comprise a line-shaped indicator 380, instead of an arrow-shaped indicator 280. During operation of the drug delivery device 200, the user may exert a force against the guard member 232 against the skin of the user until (a) no part of the first annular portion 232a of the guard member 232 is visible, and/or (b) the indicators 280, 380 (one on the second annular portion 232b and another on the distal end 212f of the housing 212) match each other. At this point, the user may hold the force applied on the guard member 232 until drug delivery is complete.

**[0079]** Additionally, or alternatively, the drug delivery device 200 may be configured to provide a tactile and/or audible feedback to the user to notify when the user should (a) stop applying force against the guard member 232 and pressing the bottom wall 252 against the injection site, and (b) maintain the input force exerted against the guard member 232 to ensure that insertion end 228 of the delivery member 216 is properly and sufficiently inserted in the injection site throughout the duration of the injection.

**[0080]** Turning now to Figs. 6A-6C, another drug delivery device 400, in accordance with various embodiments of the present disclosure, is provided. The drug delivery device 400 includes an outer casing or housing 412. The housing 412 may have a generally elongate shape, such as a cylindrical shape, and extend along a longitudinal axis A between a proximal end 412e and a distal end 412f. An opening 414 may be formed in the distal end 412f to permit an insertion end 428 of a delivery member 416 to extend outside of the housing 412 in certain configurations. A transparent or semi-transparent inspection window 417 may be positioned in a wall of the housing 412 to permit a user to view component(s) inside the drug delivery device 400, like a drug storage container similar to drug storage container 120. Although not shown, a removable cap like the removable cap 19 may cover the opening 414 prior to use of the drug delivery device 400. The drug delivery device 400 may also comprise a rear end cap 423 at the proximal end 412e of the drug delivery device 400.

**[0081]** The drug delivery device 400 may further include a guard mechanism for preventing contact with the insertion end 428 of the delivery member 416 when the drug delivery device 400 is not being used to administer an injection. The guard mechanism may include a guard member 432 moveably disposed at or near the distal end 412f of the housing 412 adjacent to the opening 440 (shown in Fig. 6A). As discussed in more detail below, the guard member 432 may be moveable relative to the housing 412 between an extended position (Fig. 6A) and a retracted position (Fig. 6B). When the guard member 432 is in the extended position (Fig. 6A), the insertion end 428 of the delivery member 416 may be surrounded by the guard member 432 such that the insertion end 428 is not visible to the user. When the guard member 432 is in the retracted position (Fig. 6B), the insertion end 428 may be at least partially exposed such that it is visible to the user and such that it can pierce through the user's skin at the injection site.

**[0082]** The guard member 432 may be hollow and generally tubular-shaped. The guard member 432 may include a first annular portion 432a and a second annular portion 432b disposed at a distal end of the first annular portion 432a. The first annular portion 432a may be hollow and generally tubular-shaped and may be a cylindrical portion centered about the longitudinal axis A. The second annular portion 432b may be disposed at a distal end of the first annular portion 432a and may also be a generally cylindrical portion centered about the longitudinal axis A. In some embodiments, the second annular portion 432b may be coupled to the first annular portion 432a. For example, the second annular portion 432b may be glued to the first annular portion 432a, or coupled to the first annular portion 432a via a snap-fit configuration or via other known mechanisms for coupling the second annular portion 432b to the first annular portion 432a. In other embodiments, the first annular portion 432a and the second annular portion 432b may be formed integrally and may define a single, monolithic structure.

**[0083]** As shown in Figs. 6A-6B, the second annular portion 432b may have an outer diameter that is greater than an outer diameter of the first annular portion 432a. In some

embodiments, the outer diameter of the second annular portion 432b may be smaller than an outer diameter of the housing 412 proximate the distal end 412f such that when the guard member 432 is in the retracted position, at least a portion of the second annular portion 432b may slide through an opening in the distal end 412f and within the housing 412. In other embodiments, the outer diameter of the second annular portion 432b may be substantially equal to or at least similar to the outer diameter of the distal end 412f of the housing 412. In this configuration, when the guard member 432 is in the retracted position, the outer diameter of the second annular portion 432b may match the outer diameter of at least the distal end 412f of the housing 412 such that the second annular portion 432b sits flush with the distal end 412f of the housing 412. The outer diameter of the first annular portion 432a may be smaller than the outer diameter of the second annular portion 432b and at least the distal end 412f of the housing 412 such that the first annular portion 432a can slide in and out of the housing 412 through an opening (such as opening 440) at the distal end 412f of the housing 412 between the extended position and the retracted position.

**[0084]** The guard member 432 may be configured to move relative to the housing 412 between the extended position wherein at least a portion of the first annular portion 432a extends through an opening 440 in the housing 412 and the retracted position wherein a shorter length or no part of the first annular portion 432a extends through the opening 440 of the housing 412. In other words, in the extended position, a length X of the first annular portion 432a may extend through the opening 440 of the housing 412 and, in the retracted position, a length Y of the first annular portion 432a may extend through the opening 440, wherein X is a value greater than Y. The length X may be any suitable number such as 10 mm, 8 mm, 6 mm, 4 mm, 2 mm, 1 mm, or another value. The length Y may be any suitable number that is less than X, such as 3 mm, 2 mm, 1 mm, 0.5 mm, 0 mm, or another value.

**[0085]** When the guard member 432 is in the extended position (Fig. 6A), the second annular portion 432b may be positioned at a first distance away from a distal end 412f of the housing 412 such that the first annular portion 432a and the second annular portion 432b may cover the insertion end 428 of the delivery member 416. The first distance may be equal to the length X of the first annular portion 432a that extends through the opening 440 of the housing 412. When the guard member 432 is in the retracted position (Fig. 6B), the first annular portion 432a may move in the proximal direction and at least a portion of the first annular portion 432a may slide into the distal end 412f of the housing 412, and the second annular portion 432b may also move in the proximal direction toward the proximal end 412e of the housing 412. Accordingly, when the guard member 432 is in the retracted position, the second annular portion 432b of the guard member 432 may be positioned a second distance (smaller than the first distance) from the distal end 412f of the housing 412 and thereby at least partially expose the insertion end 428 of the delivery member 416. The second distance may be equal to the length Y of the first annular portion 432a that extends through the opening 440 of the housing 412.

**[0086]** In some embodiments, when the guard member 432 is in the retracted position, at least a portion of the second annular portion 432b may slide into the distal end 412f of the housing 412 via the opening 440 such that no part of the first annular portion 432a is visible. In this case, when the guard member 432 is in the retracted position, the first annular portion 432a is completely disposed within the housing 412 such that no part of the first annular portion 432a is visible, and at least a portion of the second annular portion 432b is disposed within the housing 412. In yet another embodiment, and as shown in Fig. 6B, when the guard member 432 is in the retracted position, the second annular portion 432b may sit flush with the distal end 412f of the housing 412. In this configuration, the first annular portion 432a is completely disposed within the housing 412 such that no part of the first annular portion 432a is visible, and the second annular portion 432b is disposed 0 mm away from the distal end 412f of the housing 412 while no part of the second annular portion 432b is disposed inside the housing 412 (i.e., in contact with the distal end 412f of the housing 412).

**[0087]** As discussed above, the first annular portion 432a of the guard member 432 may be at least partially defined by an annular side wall, and at least a portion of the annular side wall of the first annular portion 432a may be configured to slide within the housing 412 between the extended position and the retracted position. The second annular portion 432b may be defined by an annular side wall 451, a bottom wall 452 configured to contact a skin of the user during operation of the drug delivery device 400, and a top wall 450 opposite the bottom wall 452. In some embodiments, as illustrated in Figs. 6A-6C, the top wall 450 of the second annular portion 432b may include a first curved surface (e.g., a wavy surface), and the distal end 412f of the housing 412 may also include a second curved surface that is complementary to the first curved surface. Accordingly, when the guard member 432 moves from the extended position to the retracted position, the first curved surface of the top wall 450 of the second annular portion 432b may match the second curved surface of the distal end 412f of the housing 412 (as shown in Fig. 6B) such that the first curved surface of the top wall 450 may be flush with the second curved surface of the distal end 412f of the housing 412.

**[0088]** The complementary curved surfaces of the top wall 450 of the second annular portion 432b of the guard member 432 and the distal end 412f of the housing 412 may provide a visual indication or feedback to the user of when the user should: (a) stop applying force against the guard member 432 and pressing the bottom wall 452 against the injection site, and (b) maintain the input force exerted against the guard member 432 to ensure that insertion end 428 of the delivery member 416 is properly and sufficiently inserted in the injection site throughout the duration of the injection. In particular, the user may be instructed to exert a force against the guard member 432 by pressing the bottom wall 452 of the second annular portion 432b against the skin of the user until no part of the first annular portion 432a of the guard member 432 is visible. This, in turn, can ensure proper dose administration by the user.

**[0089]** Additionally, or alternatively, the drug delivery device 400 may be configured to provide a tactile and/or audible feedback to the user to notify when the user should (a) stop applying force against the guard member 432 and pressing the bottom wall 452 against the injection site, and (b) maintain the input force exerted against the guard member 432 to ensure that insertion end 428 of the delivery member 416 is properly and sufficiently inserted in the injection site throughout the duration of the injection.

**[0090]** Turning now to Figs. 7A-7C, another drug delivery device 500, in accordance with various embodiments of the present disclosure, is provided. The drug delivery device 500 includes an outer casing or housing 512. The housing 512 may have a generally elongate shape, such as a cylindrical shape, and extend along a longitudinal axis A between a proximal end 512e and a distal end 512f. An opening 514 may be formed in the distal end 512f to permit an insertion end 528 of a delivery member 516 to extend outside of the housing 512 in certain configurations. A transparent or semi-transparent inspection window 517 may be positioned in a wall of the housing 512 to permit a user to view component(s) inside the drug delivery device 500, like a drug storage container similar to drug storage container 120. Although not shown, a removable cap like the removable cap 19 may cover the opening 514 prior to use of the drug delivery device 500. The drug delivery device 500 may also comprise a rear end cap 523 at the proximal end 512e of the drug delivery device 500.

**[0091]** The drug delivery device 500 may further include a guard mechanism for preventing contact with the insertion end 528 of the delivery member 516 when the drug delivery device 500 is not being used to administer an injection. The guard mechanism may include a guard member 532 moveably disposed at or near the distal end 512f of the housing 512 adjacent to the opening 540 (shown in Fig. 7A). As discussed in more detail below, the guard member 532 may be moveable relative to the housing 512 between an extended position (Fig. 7A) and a retracted position (Fig. 7B). When the guard member 532 is in the extended position (Fig. 7A), the insertion end 528 of the delivery member 516 may be surrounded by the guard member 532 such that the insertion end 528 is not visible to the user. When the guard member 532 is in the retracted position (Fig. 7B), the insertion end 528 may be at least partially exposed such that it is visible to the user and such that it can pierce through the user's skin at the injection site.

**[0092]** The guard member 532 may be hollow and generally tubular-shaped. The guard member 532 may include a first annular portion 532a and a second annular portion 532b disposed at a distal end of the first annular portion 532a. The first annular portion 532a may be hollow and generally tubular-shaped and may be a cylindrical portion centered about the longitudinal axis A. The second annular portion 532b may be disposed at a distal end of the first annular portion 532a and may also be a generally cylindrical portion centered about the longitudinal axis A. In some embodiments, the second annular portion 532b may be coupled to the first annular portion 532a. For example, the second annular portion 532b may be glued to the first annular portion 532a, or coupled to the first annular portion 532a via a snap-fit

configuration or via other known mechanisms for coupling the second annular portion 532b to the first annular portion 532a. In other embodiments, the first annular portion 532a and the second annular portion 532b may be formed integrally and may define a single, monolithic structure.

**[0093]** As shown in Fig. 7A, the second annular portion 532b may have an outer diameter that is greater than an outer diameter of the first annular portion 532b. In some embodiments, the outer diameter of the second annular portion 532b may be smaller than an outer diameter of the housing 512 proximate the distal end 512f such that when the guard member 532 is in the retracted position, at least a portion of the second annular portion 532b may slide through an opening in the distal end 512f and within the housing 512. In other embodiments, the outer diameter of the second annular portion 532b may be substantially equal to or at least similar to the outer diameter of the distal end 512f of the housing 512. In this configuration, when the guard member 532 is in the retracted position, the outer diameter of the second annular portion 532b may match the outer diameter of at least the distal end 512f of the housing 512 such that the second annular portion 532b sits flush with the distal end 512f of the housing 512. The outer diameter of the first annular portion 532a may be smaller than the outer diameter of the second annular portion 532b and at least the distal end 512f of the housing 512 such that the first annular portion 532a can slide in and out of the housing 512 through an opening (such as opening 540) at the distal end 512f of the housing 512 between the extended position and the retracted position.

**[0094]** The guard member 532 may be configured to move relative to the housing 512 between the extended position wherein at least a portion of the first annular portion 532a extends through an opening 540 in the housing 512 and the retracted position wherein a shorter length or no part of the first annular portion 532a extends through the opening 540 of the housing 512. In other words, in the extended position, a length X (shown in Fig. 7A) of the first annular portion 532a may extend through the opening 540 of the housing 512 and, in the retracted position, a length Y (shown in Fig. 7B) of the first annular portion 532a may extend through the opening 540, wherein X is a value greater than Y. The length X may be any suitable number such as 10 mm, 8 mm, 6 mm, 4 mm, 2 mm, 1 mm, or another value. The length Y may be any suitable number that is less than X, such as 3 mm, 2 mm, 1 mm, 0.5 mm, 0 mm, or another value.

**[0095]** When the guard member 532 is in the extended position (Fig. 7A), the second annular portion 532b may be positioned at a first distance away from a distal end 512f of the housing 512 such that the first annular portion 532a and the second annular portion 532b may cover the insertion end 528 of the delivery member 516. The first distance may be equal to the length X of the first annular portion 532a that extends through the opening 540 of the housing 512. When the guard member 532 is in the retracted position, the first annular portion 532a may move in the proximal direction and at least a portion of the first annular portion 532a may slide into the

distal end 512f of the housing 512, and the second annular portion 532b may also move in the proximal direction toward the proximal end 512e of the housing 512. Accordingly, when the guard member 532 is in the retracted position (Fig. 7B), the second annular portion 532b of the guard member 532 may be positioned a second distance (smaller than the first distance) from the distal end 512f of the housing 512 and thereby at least partially expose the insertion end 528 of the delivery member 516. The second distance may be equal to the length Y of the first annular portion 532a that extends through the opening 540 of the housing 512.

**[0096]** In some embodiments, when the guard member 532 is in the retracted position, at least a portion of the second annular portion 532b may slide into the distal end 512f of the housing 512 via the opening 540 such that no part of the first annular portion 532a is visible. In this case, when the guard member 532 is in the retracted position, the first annular portion 532a is completely disposed within the housing 512 such that no part of the first annular portion 532a is visible, and at least a portion of the second annular portion 532b is disposed within the housing 512. In another embodiment, when the guard member 532 is in the retracted position, the second annular portion 532b may sit flush with the distal end 512f of the housing 512. In this configuration, the first annular portion 532a is completely disposed within the housing 512 such that no part of the first annular portion 532a is visible, and the second annular portion 532b is disposed 0 mm away from the distal end 512f of the housing 512 while no part of the second annular portion 532b is disposed inside the housing 512 (i.e., in contact with the distal end 512f of the housing 512).

**[0097]** As discussed above, the first annular portion 532a of the guard member 532 may be at least partially defined by an annular side wall, and at least a portion of the annular side wall of the first annular portion 532a may be configured to slide within the housing 512 between the extended position and the retracted position. The second annular portion 532b may be defined by an annular side wall 551, a bottom wall 552 configured to contact a skin of the user during operation of the drug delivery device 500, and a top wall 550 opposite the bottom wall 552. In some embodiments, as illustrated in Figs. 7A-7C, the top wall 550 of the second annular portion 532b may include a first ramped or inclined surface, and the distal end 512f of the housing 512 may also include a second ramped surface that is complementary to the first ramped surface. Accordingly, when the guard member 532 moves from the extended position to the retracted position, the first ramped surface of the top wall 550 of the second annular portion 532b may match the second ramped surface of the distal end 512f of the housing 512 such that the first ramped surface of the top wall 550 may be flush with the second ramped surface of the distal end 512f of the housing 512.

**[0098]** The complementary ramped surfaces of the top wall 550 of the second annular portion 532b of the guard member 532 and the distal end 512f of the housing 512 may provide a visual indication or feedback to the user of when the user should: (a) stop applying force against the guard member 532 and pressing the bottom wall 552 against the injection site, and (b) maintain

the input force exerted against the guard member 532 to ensure that insertion end 528 of the delivery member 516 is properly and sufficiently inserted in the injection site throughout the duration of the injection. In particular, the user may be instructed to exert a force against the guard member 532 by pressing the bottom wall 552 of the second annular portion 532b against the skin of the user until no part of the first annular portion 532a of the guard member 532 is visible. This, in turn, can ensure proper dose administration by the user.

**[0099]** Additionally, or alternatively, the drug delivery device 500 may be configured to provide a tactile and/or audible feedback to the user to notify when the user should (a) stop applying force against the guard member 532 and pressing the bottom wall 552 against the injection site, and (b) maintain the input force exerted against the guard member 532 to ensure that insertion end 528 of the delivery member 516 is properly and sufficiently inserted in the injection site throughout the duration of the injection.

**[0100]** From the foregoing, it can be seen that the present disclosure advantageously provides an improved design for a drug delivery device having a needle shield or guard with a visual feedback for indicating to the user when the user should hold a force exerted against the needle shield at the injection site to ensure proper dose administration, as well as provide other benefits and advantages. All features disclosed herein with respect to any of the needle shield embodiments may be combined in any combination, except combinations where at least some of such features are mutually exclusive.

**[0101]** As will be recognized, the devices and methods according to the present disclosure may have one or more advantages relative to conventional technology, any one or more of which may be present in a particular embodiment in accordance with the features of the present disclosure included in that embodiment. Other advantages not specifically listed herein may also be recognized as well.

**[0102]** The above description describes various devices, assemblies, components, subsystems and methods for use related to a drug delivery device. The devices, assemblies, components, subsystems, methods or drug delivery devices can further comprise or be used with a drug including but not limited to those drugs identified below as well as their generic and biosimilar counterparts. The term drug, as used herein, can be used interchangeably with other similar terms and can be used to refer to any type of medicament or therapeutic material including traditional and non-traditional pharmaceuticals, nutraceuticals, supplements, biologics, biologically active agents and compositions, large molecules, biosimilars, bioequivalents, therapeutic antibodies, polypeptides, proteins, small molecules and generics. Non-therapeutic injectable materials are also encompassed. The drug may be in liquid form, a lyophilized form, or in a reconstituted from lyophilized form. The following example list of drugs should not be considered as all-inclusive or limiting.

**[0103]** The drug will be contained in a reservoir. In some instances, the reservoir is a primary container that is either filled or pre-filled for treatment with the drug. The primary container can be a vial, a cartridge or a pre-filled syringe.

**[0104]** In some embodiments, the reservoir of the drug delivery device may be filled with or the device can be used with colony stimulating factors, such as granulocyte colony-stimulating factor (G-CSF). Such G-CSF agents include but are not limited to Neulasta® (pegfilgrastim, pegylated filgrastim, pegylated G-CSF, pegylated hu-Met-G-CSF) and Neupogen® (filgrastim, G-CSF, hu-MetG-CSF), Udenyca® (pegfilgrastim-cbqv), Zientenzo® (LA-EP2006; pegfilgrastim-bmez), or FULPHILA (pegfilgrastim-bmez).

**[0105]** In other embodiments, the drug delivery device may contain or be used with an erythropoiesis stimulating agent (ESA), which may be in liquid or lyophilized form. An ESA is any molecule that stimulates erythropoiesis. In some embodiments, an ESA is an erythropoiesis stimulating protein. As used herein, "erythropoiesis stimulating protein" means any protein that directly or indirectly causes activation of the erythropoietin receptor, for example, by binding to and causing dimerization of the receptor. Erythropoiesis stimulating proteins include erythropoietin and variants, analogs, or derivatives thereof that bind to and activate erythropoietin receptor; antibodies that bind to erythropoietin receptor and activate the receptor; or peptides that bind to and activate erythropoietin receptor. Erythropoiesis stimulating proteins include, but are not limited to, Epogen® (epoetin alfa), Aranesp® (darbepoetin alfa), Dynepo® (epoetin delta), Mircera® (methoxy polyethylene glycol-epoetin beta), Hematide®, MRK-2578, INS-22, Retacrit® (epoetin zeta), Neorecormon® (epoetin beta), Silapo® (epoetin zeta), Binocrit® (epoetin alfa), epoetin alfa Hexal, Abseamed® (epoetin alfa), Ratioepo® (epoetin theta), Eporatio® (epoetin theta), Biopoin® (epoetin theta), epoetin alfa, epoetin beta, epoetin iota, epoetin omega, epoetin delta, epoetin zeta, epoetin theta, and epoetin delta, pegylated erythropoietin, carbamylated erythropoietin, as well as the molecules or variants or analogs thereof.

**[0106]** Among particular illustrative proteins are the specific proteins set forth below, including fusions, fragments, analogs, variants or derivatives thereof: OPGL specific antibodies, peptibodies, related proteins, and the like (also referred to as RANKL specific antibodies, peptibodies and the like), including fully humanized and human OPGL specific antibodies, particularly fully humanized monoclonal antibodies; Myostatin binding proteins, peptibodies, related proteins, and the like, including myostatin specific peptibodies; IL-4 receptor specific antibodies, peptibodies, related proteins, and the like, particularly those that inhibit activities mediated by binding of IL-4 and/or IL-13 to the receptor; Interleukin 1-receptor 1 ("IL1-R1") specific antibodies, peptibodies, related proteins, and the like; Ang2 specific antibodies, peptibodies, related proteins, and the like; NGF specific antibodies, peptibodies, related proteins, and the like; CD22 specific antibodies, peptibodies, related proteins, and the like, particularly human CD22 specific antibodies, such as but not limited to humanized and fully

human antibodies, including but not limited to humanized and fully human monoclonal antibodies, particularly including but not limited to human CD22 specific IgG antibodies, such as, a dimer of a human-mouse monoclonal hLL2 gamma-chain disulfide linked to a human-mouse monoclonal hLL2 kappa-chain, for example, the human CD22 specific fully humanized antibody in Epratuzumab, CAS registry number 501423-23-0; IGF-1 receptor specific antibodies, peptibodies, and related proteins, and the like including but not limited to anti-IGF-1R antibodies; B-7 related protein 1 specific antibodies, peptibodies, related proteins and the like ("B7RP-1" and also referring to B7H2, ICOSL, B7h, and CD275), including but not limited to B7RP-specific fully human monoclonal IgG2 antibodies, including but not limited to fully human IgG2 monoclonal antibody that binds an epitope in the first immunoglobulin-like domain of B7RP-1, including but not limited to those that inhibit the interaction of B7RP-1 with its natural receptor, ICOS, on activated T cells; IL-15 specific antibodies, peptibodies, related proteins, and the like, such as, in particular, humanized monoclonal antibodies, including but not limited to HuMax IL-15 antibodies and related proteins, such as, for instance, 145c7; IFN gamma specific antibodies, peptibodies, related proteins and the like, including but not limited to human IFN gamma specific antibodies, and including but not limited to fully human anti-IFN gamma antibodies; TALL-1 specific antibodies, peptibodies, related proteins, and the like, and other TALL specific binding proteins; Parathyroid hormone ("PTH") specific antibodies, peptibodies, related proteins, and the like; Thrombopoietin receptor ("TPO-R") specific antibodies, peptibodies, related proteins, and the like; Hepatocyte growth factor ("HGF") specific antibodies, peptibodies, related proteins, and the like, including those that target the HGF/SF:cMet axis (HGF/SF:cMet), such as fully human monoclonal antibodies that neutralize hepatocyte growth factor/scatter (HGF/SF); TRAIL-R2 specific antibodies, peptibodies, related proteins and the like; Activin A specific antibodies, peptibodies, proteins, and the like; TGF-beta specific antibodies, peptibodies, related proteins, and the like; Amyloid-beta protein specific antibodies, peptibodies, related proteins, and the like; c-Kit specific antibodies, peptibodies, related proteins, and the like, including but not limited to proteins that bind c-Kit and/or other stem cell factor receptors; OX40L specific antibodies, peptibodies, related proteins, and the like, including but not limited to proteins that bind OX40L and/or other ligands of the OX40 receptor; Activase® (alteplase, tPA); Aranesp® (darbepoetin alfa) Erythropoietin [30-asparagine, 32-threonine, 87-valine, 88-asparagine, 90-threonine], Darbepoetin alfa, novel erythropoiesis stimulating protein (NESP); Epogen® (epoetin alfa, or erythropoietin); GLP-1, Avonex® (interferon beta-1a); Bexxar® (tositumomab, anti-CD22 monoclonal antibody); Betaseron® (interferon-beta); Campath® (alemtuzumab, anti-CD52 monoclonal antibody); Dynepo® (epoetin delta); Velcade® (bortezomib); MLN0002 (anti-  $\alpha$ 4 $\beta$ 7 mAb); MLN1202 (anti-CCR2 chemokine receptor mAb); Enbrel® (etanercept, TNF-receptor /Fc fusion protein, TNF blocker); Eprex® (epoetin alfa); Erbitux® (cetuximab, anti-EGFR / HER1 / c-ErbB-1); Genotropin® (somatropin, Human Growth Hormone); Herceptin® (trastuzumab, anti-HER2/neu (erbB2) receptor mAb); Kanjinti™ (trastuzumab-anns) anti-HER2 monoclonal

antibody, biosimilar to Herceptin®, or another product containing trastuzumab for the treatment of breast or gastric cancers; Humatrope® (somatropin, Human Growth Hormone); Humira® (adalimumab); Vectibix® (panitumumab), Xgeva® (denosumab), Prolia® (denosumab), Immunoglobulin G2 Human Monoclonal Antibody to RANK Ligand, Enbrel® (etanercept, TNF-receptor /Fc fusion protein, TNF blocker), Nplate® (romiplostim), rilatumumab, ganitumab, conatumumab, brodalumab, insulin in solution; Infergen® (interferon alfacon-1); Natrecor® (nesiritide; recombinant human B-type natriuretic peptide (hBNP); Kineret® (anakinra); Leukine® (sargamostim, rhuGM-CSF); LymphoCide® (epratuzumab, anti-CD22 mAb); Benlysta™ (lymphostatin B, belimumab, anti-BlyS mAb); Metalyse® (tenecteplase, t-PA analog); Mircera® (methoxy polyethylene glycol-epoetin beta); Mylotarg® (gemtuzumab ozogamicin); Raptiva® (efalizumab); Cimzia® (certolizumab pegol, CDP 870); Soliris™ (eculizumab); pexelizumab (anti-C5 complement); Numax® (MEDI-524); Lucentis® (ranibizumab); Panorex® (17-1A, edrecolomab); Trabio® (lerdelimumab); TheraCim hR3 (nimotuzumab); Omnitarg (pertuzumab, 2C4); Osidem® (IDM-1); OvaRex® (B43.13); Nuvion® (visilizumab); cantuzumab mertansine (huC242-DM1); NeoRecormon® (epoetin beta); Neumega® (oprelvekin, human interleukin-11); Orthoclone OKT3® (muromonab-CD3, anti-CD3 monoclonal antibody); Procrit® (epoetin alfa); Remicade® (infliximab, anti-TNF $\alpha$  monoclonal antibody); Reopro® (abciximab, anti-GP IIb/IIIa receptor monoclonal antibody); Actemra® (anti-IL6 Receptor mAb); Avastin® (bevacizumab), HuMax-CD4 (zanolimumab); Mvasi™ (bevacizumab-awwb); Rituxan® (rituximab, anti-CD20 mAb); Tarceva® (erlotinib); Roferon-A® (interferon alfa-2a); Simulect® (basiliximab); Prexige® (lumiracoxib); Synagis® (palivizumab); 145c7-CHO (anti-IL15 antibody, see U.S. Patent No. 7,153,507); Tysabri® (natalizumab, anti- $\alpha$ 4 integrin mAb); Valortim® (MDX-1303, anti-B. anthracis protective antigen mAb); ABthrax™; Xolair® (omalizumab); ETI211 (anti-MRSA mAb); IL-1 trap (the Fc portion of human IgG1 and the extracellular domains of both IL-1 receptor components (the Type I receptor and receptor accessory protein)); VEGF trap (Ig domains of VEGFR1 fused to IgG1 Fc); Zenapax® (daclizumab); Zenapax® (daclizumab, anti-IL-2R $\alpha$  mAb); Zevalin® (ibritumomab tiuxetan); Zetia® (ezetimibe); Orencia® (atacept, TACI-Ig); anti-CD80 monoclonal antibody (galiximab); anti-CD23 mAb (lumiliximab); BR2-Fc (huBR3 / huFc fusion protein, soluble BAFF antagonist); CNTO 148 (golimumab, anti-TNF $\alpha$  mAb); HGS-ETR1 (mapatumumab; human anti-TRAIL Receptor-1 mAb); HuMax-CD20 (ocrelizumab, anti-CD20 human mAb); HuMax-EGFR (zalutumumab); M200 (volociximab, anti- $\alpha$ 5 $\beta$ 1 integrin mAb); MDX-010 (ipilimumab, anti-CTLA-4 mAb and VEGFR-1 (IMC-18F1); anti-BR3 mAb; anti-C. difficile Toxin A and Toxin B C mAbs MDX-066 (CDA-1) and MDX-1388); anti-CD22 dsFv-PE38 conjugates (CAT-3888 and CAT-8015); anti-CD25 mAb (HuMax-TAC); anti-CD3 mAb (NI-0401); adecatumumab; anti-CD30 mAb (MDX-060); MDX-1333 (anti-IFNAR); anti-CD38 mAb (HuMax CD38); anti-CD40L mAb; anti-Cripto mAb; anti-CTGF Idiopathic Pulmonary Fibrosis Phase I Fibrogen (FG-3019); anti-CTLA4 mAb; anti-eotaxin1 mAb (CAT-213); anti-FGF8 mAb; anti-ganglioside GD2 mAb; anti-ganglioside GM2 mAb; anti-GDF-8 human mAb (MYO-029); anti-

GM-CSF Receptor mAb (CAM-3001); anti-HepC mAb (HuMax HepC); anti-IFN $\alpha$  mAb (MEDI-545, MDX-198); anti-IGF1R mAb; anti-IGF-1R mAb (HuMax-Inflam); anti-IL12 mAb (ABT-874); anti-IL12/IL23 mAb (CNTO 1275); anti-IL13 mAb (CAT-354); anti-IL2Ra mAb (HuMax-TAC); anti-IL5 Receptor mAb; anti-integrin receptors mAb (MDX-018, CNTO 95); anti-IP10 Ulcerative Colitis mAb (MDX-1100); BMS-66513; anti-Mannose Receptor/hCG $\beta$  mAb (MDX-1307); anti-mesothelin dsFv-PE38 conjugate (CAT-5001); anti-PD1mAb (MDX-1106 (ONO-4538)); anti-PDGFR $\alpha$  antibody (IMC-3G3); anti-TGF $\beta$  mAb (GC-1008); anti-TRAIL Receptor-2 human mAb (HGS-ETR2); anti-TWEAK mAb; anti-VEGFR/Flt-1 mAb; and anti-ZP3 mAb (HuMax-ZP3).

**[0107]** In some embodiments, the drug delivery device may contain or be used with a sclerostin antibody, such as but not limited to romosozumab, blosozumab, BPS 804 (Novartis), Evenity™ (romosozumab-aqqg), another product containing romosozumab for treatment of postmenopausal osteoporosis and/or fracture healing and in other embodiments, a monoclonal antibody (IgG) that binds human Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9). Such PCSK9 specific antibodies include, but are not limited to, Repatha® (evolocumab) and Praluent® (alirocumab). In other embodiments, the drug delivery device may contain or be used with rilotumumab, bixalomer, trebananib, ganitumab, conatumumab, motesanib diphosphate, brodalumab, vidupirant or panitumumab. In some embodiments, the reservoir of the drug delivery device may be filled with or the device can be used with IMLYGIC® (talimogene laherparepvec) or another oncolytic HSV for the treatment of melanoma or other cancers including but are not limited to OncoVEXGALV/CD; OrienX010; G207, 1716; NV1020; NV12023; NV1034; and NV1042. In some embodiments, the drug delivery device may contain or be used with endogenous tissue inhibitors of metalloproteinases (TIMPs) such as but not limited to TIMP-3. In some embodiments, the drug delivery device may contain or be used with Aimovig® (erenumab-aooe), anti-human CGRP-R (calcitonin gene-related peptide type 1 receptor) or another product containing erenumab for the treatment of migraine headaches. Antagonistic antibodies for human calcitonin gene-related peptide (CGRP) receptor such as but not limited to erenumab and bispecific antibody molecules that target the CGRP receptor and other headache targets may also be delivered with a drug delivery device of the present disclosure. Additionally, bispecific T cell engager (BiTE®) antibodies such as but not limited to BLINCYTO® (blinatumomab) can be used in or with the drug delivery device of the present disclosure. In some embodiments, the drug delivery device may contain or be used with an APJ large molecule agonist such as but not limited to apelin or analogues thereof. In some embodiments, a therapeutically effective amount of an anti-thymic stromal lymphopoietin (TSLP) or TSLP receptor antibody is used in or with the drug delivery device of the present disclosure. In some embodiments, the drug delivery device may contain or be used with Avsola™ (infliximab-axxq), anti-TNF  $\alpha$  monoclonal antibody, biosimilar to Remicade® (infliximab) (Janssen Biotech, Inc.) or another product containing infliximab for the treatment of autoimmune diseases. In some embodiments, the drug delivery device may contain or be used with Kyprolis® (carfilzomib),

(2S)-N-((S)-1-((S)-4-methyl-1-((R)-2-methyloxiran-2-yl)-1-oxopentan-2-ylcarbamoyl)-2-phenylethyl)-2-((S)-2-(2-morpholinoacetamido)-4-phenylbutanamido)-4-methylpentanamide, or another product containing carfilzomib for the treatment of multiple myeloma. In some embodiments, the drug delivery device may contain or be used with Otezla® (apremilast), N-[2-[(1S)-1-(3-ethoxy-4-methoxyphenyl)-2-(methylsulfonyl)ethyl]-2,3-dihydro-1H-isindol-4-yl]acetamide, or another product containing apremilast for the treatment of various inflammatory diseases. In some embodiments, the drug delivery device may contain or be used with Parsabiv™ (etelcalcetide HCl, KAI-4169) or another product containing etelcalcetide HCl for the treatment of secondary hyperparathyroidism (sHPT) such as in patients with chronic kidney disease (KD) on hemodialysis. In some embodiments, the drug delivery device may contain or be used with ABP 798 (rituximab), a biosimilar candidate to Rituxan®/MabThera™, or another product containing an anti-CD20 monoclonal antibody. In some embodiments, the drug delivery device may contain or be used with a VEGF antagonist such as a non-antibody VEGF antagonist and/or a VEGF-Trap such as aflibercept (Ig domain 2 from VEGFR1 and Ig domain 3 from VEGFR2, fused to Fc domain of IgG1). In some embodiments, the drug delivery device may contain or be used with ABP 959 (eculizumab), a biosimilar candidate to Soliris®, or another product containing a monoclonal antibody that specifically binds to the complement protein C5. In some embodiments, the drug delivery device may contain or be used with Rozibafusp alfa (formerly AMG 570) is a novel bispecific antibody-peptide conjugate that simultaneously blocks ICOSL and BAFF activity. In some embodiments, the drug delivery device may contain or be used with Omecamtiv mecarbil, a small molecule selective cardiac myosin activator, or myotrope, which directly targets the contractile mechanisms of the heart, or another product containing a small molecule selective cardiac myosin activator. In some embodiments, the drug delivery device may contain or be used with Sotorasib (formerly known as AMG 510), a KRAS<sup>G12C</sup> small molecule inhibitor, or another product containing a KRAS<sup>G12C</sup> small molecule inhibitor. In some embodiments, the drug delivery device may contain or be used with Tezepelumab, a human monoclonal antibody that inhibits the action of thymic stromal lymphopoietin (TSLP), or another product containing a human monoclonal antibody that inhibits the action of TSLP. In some embodiments, the drug delivery device may contain or be used with rocatinlimab (AMG 451), a human anti-OX40 monoclonal antibody that is expressed on activated T cells and blocks OX40 to inhibit and/or reduce the number of OX40 pathogenic T cells that are responsible for driving system and local atopic dermatitis inflammatory responses. In some embodiments, the drug delivery device may contain or be used with AMG 714, a human monoclonal antibody that binds to Interleukin-15 (IL-15) or another product containing a human monoclonal antibody that binds to Interleukin-15 (IL-15). In some embodiments, the drug delivery device may contain or be used with AMG 890, a small interfering RNA (siRNA) that lowers lipoprotein(a), also known as Lp(a), or another product containing a small interfering RNA (siRNA) that lowers lipoprotein(a). In some embodiments, the drug delivery device may contain

or be used with ABP 654 (human IgG1 kappa antibody), a biosimilar candidate to Stelara®, or another product that contains human IgG1 kappa antibody and/or binds to the p40 subunit of human cytokines interleukin (IL)-12 and IL-23. In some embodiments, the drug delivery device may contain or be used with Amjevita™ or Amgevita™ (formerly ABP 501) (mab anti-TNF human IgG1), a biosimilar candidate to Humira®, or another product that contains human mab anti-TNF human IgG1. In some embodiments, the drug delivery device may contain or be used with AMG 160, or another product that contains a half-life extended (HLE) anti-prostate-specific membrane antigen (PSMA) x anti-CD3 BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with AMG 119, or another product containing a delta-like ligand 3 (DLL3) CAR T (chimeric antigen receptor T cell) cellular therapy. In some embodiments, the drug delivery device may contain or be used with AMG 119, or another product containing a delta-like ligand 3 (DLL3) CAR T (chimeric antigen receptor T cell) cellular therapy. In some embodiments, the drug delivery device may contain or be used with AMG 133, or another product containing a gastric inhibitory polypeptide receptor (GIPR) antagonist and GLP-1R agonist. In some embodiments, the drug delivery device may contain or be used with AMG 171 or another product containing a Growth Differential Factor 15 (GDF15) analog. In some embodiments, the drug delivery device may contain or be used with AMG 176 or another product containing a small molecule inhibitor of myeloid cell leukemia 1 (MCL-1). In some embodiments, the drug delivery device may contain or be used with AMG 199 or another product containing a half-life extended (HLE) bispecific T cell engager construct (BiTE®). In some embodiments, the drug delivery device may contain or be used with AMG 256 or another product containing an anti-PD-1 x IL21 mutein and/or an IL-21 receptor agonist designed to selectively turn on the Interleukin 21 (IL-21) pathway in programmed cell death-1 (PD-1) positive cells. In some embodiments, the drug delivery device may contain or be used with AMG 330 or another product containing an anti-CD33 x anti-CD3 BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with AMG 404 or another product containing a human anti-programmed cell death-1(PD-1) monoclonal antibody being investigated as a treatment for patients with solid tumors. In some embodiments, the drug delivery device may contain or be used with AMG 427 or another product containing a half-life extended (HLE) anti-fms-like tyrosine kinase 3 (FLT3) x anti-CD3 BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with AMG 430 or another product containing an anti-Jagged-1 monoclonal antibody. In some embodiments, the drug delivery device may contain or be used with AMG 506 or another product containing a multi-specific FAP x 4-1BB-targeting DARPIn® biologic under investigation as a treatment for solid tumors. In some embodiments, the drug delivery device may contain or be used with AMG 509 or another product containing a bivalent T-cell engager and is designed using XmAb® 2+1 technology. In some embodiments, the drug delivery device may contain or be used with AMG 562 or another product containing a half-life extended (HLE) CD19 x CD3

BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with Efavaleukin alfa (formerly AMG 592) or another product containing an IL-2 mutein Fc fusion protein. In some embodiments, the drug delivery device may contain or be used with AMG 596 or another product containing a CD3 x epidermal growth factor receptor vIII (EGFRvIII) BiTE® (bispecific T cell engager) molecule. In some embodiments, the drug delivery device may contain or be used with AMG 673 or another product containing a half-life extended (HLE) anti-CD33 x anti-CD3 BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with AMG 701 or another product containing a half-life extended (HLE) anti-B-cell maturation antigen (BCMA) x anti-CD3 BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with AMG 757 or another product containing a half-life extended (HLE) anti- delta-like ligand 3 (DLL3) x anti-CD3 BiTE® (bispecific T cell engager) construct. In some embodiments, the drug delivery device may contain or be used with AMG 910 or another product containing a half-life extended (HLE) epithelial cell tight junction protein claudin 18.2 x CD3 BiTE® (bispecific T cell engager) construct.

**[0108]** Although the drug delivery devices, assemblies, components, subsystems and methods have been described in terms of exemplary embodiments, they are not limited thereto. The detailed description is to be construed as exemplary only and does not describe every possible embodiment of the present disclosure. Numerous alternative embodiments could be implemented, using either current technology or technology developed after the filing date of this patent that would still fall within the scope of the claims defining the invention(s) disclosed herein.

**[0109]** Those skilled in the art will recognize that a wide variety of modifications, alterations, and combinations can be made with respect to the above described embodiments without departing from the spirit and scope of the invention(s) disclosed herein, and that such modifications, alterations, and combinations are to be viewed as being within the ambit of the inventive concept(s).

What is claimed is:

1. A drug delivery device comprising:
  - a housing defining a longitudinal axis and having an opening;
  - a drug storage container including a delivery member, the delivery member having an insertion end configured to extend at least partially through the opening during a delivery state;
  - a plunger moveable toward a distal end of the drug storage container to expel a drug from the drug storage container through the delivery member; and
  - a guard disposed adjacent the opening in the housing and moveable relative to the housing between an extended position and a retracted position, wherein the insertion end of the delivery member is surrounded by the guard in the extended position and the insertion end is at least partially exposed in the retracted position,
    - wherein the guard includes a first annular portion and a second annular portion disposed at a distal end of the first annular portion, the second annular portion having an outer diameter greater than an outer diameter of the first annular portion,
    - wherein the second annular portion is positioned a first distance from a distal end of the housing when the guard is in the extended position and the second annular portion is positioned a second distance from the distal end of the housing when the guard is in the retracted position, the second distance being smaller than the first distance.
2. The drug delivery device of claim 1, wherein the second annular portion is defined by an annular side wall, a bottom wall configured to contact a skin of a user, and a top wall opposite the bottom wall.
3. The drug delivery device of claim 2, wherein the top wall includes a first ramped surface, and the distal end of the housing includes a second ramped surface that is complementary to the first ramped surface.
4. The drug delivery device of claim 2, wherein the top wall includes a first stepped surface, and the distal end of the housing includes a second stepped surface that is complementary to the first stepped surface.
5. The drug delivery device of claim 2, wherein the top wall includes a first curved surface, and the distal end of the housing includes a second curved surface that is complementary to the first curved surface.

6. The drug delivery device of claim 2, wherein at least a portion of the annular side wall of the first annular portion is configured to slide within the housing when the guard is in the retracted position.

7. The drug delivery device of claim 1, wherein the outer diameter of the second annular portion is substantially the same as an outer diameter of the housing.

8. The drug delivery device of claim 1, wherein the outer diameter of the second annular portion is smaller than an outer diameter of the housing.

9. The drug delivery device of claim 1, wherein the first annular portion of the guard is at least partially defined by an annular side wall, and wherein the annular side wall of the first annular portion is configured to slide within the housing between the extended position and the retracted position.

10. The drug delivery device of claim 1, wherein the second annular portion is coupled to the first annular portion.

11. The drug delivery device of claim 1, wherein the first annular portion and the second annular portion are defined by a single, monolithic structure.

12. The drug delivery device of claim 1, further comprising a plunger guide fixed relative to the housing, the plunger being disposed at least partially within the plunger guide.

13. The drug delivery device of claim 12, further comprising:  
a releaser member operably coupled to the plunger and configured to selectively rotate relative to the housing, wherein each of the plunger and the plunger guide is disposed at least partially within the releaser member; and  
the guard is operably coupled to the releaser member.

14. The drug delivery device of claim 13, wherein the releaser member is prevented from rotating in at least one rotational direction when the guard is in the extended position, and wherein the releaser member is allowed to rotate in the at least one rotational direction when the guard is in the retracted position.

15. The drug delivery device of claim 14, wherein moving the guard from the extended position to the retracted position allows the releaser member and the plunger to rotate jointly

from a first rotational position toward a second rotational position under a biasing force exerted by a biasing member.

16. The drug delivery device of claim 1, further comprising a lock ring configured to rotate between a first rotational position and a second rotational position, wherein a rotational position of the lock ring is based on an axial position of the guard.

17. The drug delivery device of claim 16, wherein a distal end of the lock ring is disposed at least partially within the guard.

18. The drug delivery device of claim 16, further comprising a lock ring biasing member positioned between the lock ring and a bottom wall of the second annular portion of the guard.

19. The drug delivery device of claim 18, wherein the lock ring biasing member is positioned within the first annular portion of the guard.

20. The drug delivery device of claim 16, wherein the lock ring biasing member is a compression spring configured to exert a biasing force on the guard to urge the guard toward the extended position.

21. A method of delivering a drug, comprising:

providing a drug delivery device including a housing, a drug storage container having a delivery member with an insertion end, a plunger moveable toward a distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, and a guard moveable relative to the housing between an extended position and a retracted position, wherein the guard includes a first annular portion and a second annular portion disposed at a distal end of the first annular portion, the second annular portion having an outer diameter greater than an outer diameter of the first annular portion;

placing the drug delivery device such that the second annular portion of the guard abuts an injection site; and

applying a force to the housing toward the injection site to permit movement of the guard from the extended position to the retracted position,

wherein the second annular portion is positioned a first distance from a distal end of the housing when the guard is in the extended position and the second annular portion is positioned a second distance from the distal end of the housing when the guard is in the retracted position, the second distance being smaller than the first distance.