

DRUG DELIVERY DEVICES AND RELATED METHODS**CROSS-REFERENCE TO RELATED APPLICATIONS**

[0001] The present application claims priority to U.S. Provisional Patent Application No. 63/585,949, filed September 27, 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.

BACKGROUND

[0003] Some individuals may not be comfortable with needles or their use in performing an injection. This general aversion to needles, along with other concerns related to health and safety, has prompted the development of drug delivery devices which conceal a needle or other insertion member prior to use and automate various aspects of the injection process. Such devices offer a variety of benefits as compared with traditional forms of drug delivery including, for example, delivery via a regular syringe.

[0004] Some drug delivery devices, including, for example, some autoinjectors, may include a spring biased guard to hide the needle prior to and/or after an injection. To uncover the needle, the user may press the guard against the skin at the injection site to move the guard from an extended position to a retracted position, such that the tip of the needle is or can be exposed for insertion. During the injection, the user continues to press the guard against the skin to hold the guard in the retracted position. This requires the user to apply a force counteracting the biasing force of the guard spring over the course of the injection. This can be challenging for at least some individuals, including, for example, those performing a self-injection and/or having a limited familiarity with injections. In certain cases, the force of the guard spring may cause or encourage the user to lift the device off of the skin prior to the end of drug delivery, potentially resulting in incomplete delivery of a dose of the drug. Moreover, sustaining the counteracting force may cause the user to inadvertently move the needle laterally with respect to the skin, which can cause discomfort to the patient.

[0005] The present disclosure sets forth drug delivery devices and related methods to address one or one of the needs and challenges mentioned herein and other related needs and challenges.

SUMMARY

[0006] One aspect of the present disclosure provides a drug delivery device. The drug delivery device may include a housing, a drug storage container, a guard, a plunger, a plunger biasing member, and a proximal biasing member. The housing may have an opening and a longitudinal axis. 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 in a distal direction along the longitudinal axis to expel a drug from the drug storage container through the delivery member

during the delivery state. The plunger biasing member may be configured to bias the plunger in the distal direction. The guard positioned adjacent to the opening and having a first axial position with respect to the housing prior to the delivery state and a second axial position with respect to the housing during the delivery state. The proximal biasing member may be configured to selectively bias the guard in the distal direction.

[0007] Another aspect of the present disclosure provides a method. The method may include providing a drug delivery device comprising a housing having an opening and a longitudinal axis, a drug storage container having an insertion end configured to extend at least partially through the opening during a delivery state, a plunger moveable in a distal direction along the longitudinal axis to expel a drug from the drug storage container through the delivery member during the delivery state, a plunger biasing member configured to bias the plunger in the distal direction, a guard positioned adjacent to the opening and having a first axial position with respect to the housing prior to the delivery state and a second axial position with respect to the housing during the delivery state, and a proximal biasing member configured to selectively bias the guard in the distal direction. The method may additionally include moving the guard in a proximal direction from the first axial position to the second axial position while the proximal biasing member biases the guard in the distal direction. Furthermore, the method may include holding the guard in the second axial position while the proximal biasing member at least temporarily ceases biasing, or biases less, the guard in the distal direction.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] 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 drawn to scale.

[0009] Fig. 1A is a perspective view of a drug delivery device in accordance with various embodiments, in a storage state.

[0010] Fig. 1B is a perspective view of the drug delivery device in Fig. 1A, in a pre-delivery state.

[0011] Fig. 1C is a perspective view of the drug delivery device in Fig. 1A, in a delivery state.

[0012] Fig. 2 is cross-sectional view of the drug delivery device in Fig. 1A, in the delivery state.

[0013] Fig. 3A is an exploded assembly view of the drug delivery device in Fig. 1A.

[0014] Fig. 3B is an exploded assembly view of the drive mechanism in Fig. 3A.

[0015] Fig. 4A is a perspective view of the plunger guide in Fig. 3B.

[0016] Fig. 4B is a top view of the plunger guide in Fig. 4A.

[0017] Figs. 5A and 5B are perspective views of the releaser member in Fig. 3B.

- [0018]** Figs. 6A and 6B are perspective views of the rotatable member in Fig. 3B.
- [0019]** Fig. 7A illustrates a side view of portions of the drug delivery device in Fig. 3A, namely the drive mechanism and guard, in the storage state.
- [0020]** Fig. 7B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 7A.
- [0021]** Fig. 8A illustrates a side view of portions of the drug delivery device in Fig. 3A, namely the drive mechanism and guard, in an initial portion of the delivery state. The rotatable member in Fig. 8A is illustrated as being semi-transparent.
- [0022]** Fig. 8B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 8A.
- [0023]** Fig. 9A illustrates a side view of portions of the drug delivery device in Fig. 3A, namely the drive mechanism and guard, in a portion of the delivery state after the portion of the delivery state in Fig. 8A.
- [0024]** Fig. 9B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 9A.
- [0025]** Fig. 10A illustrates a side view of portions of the drug delivery device in Fig. 3A, namely the drive mechanism and guard, in a portion of the delivery state after the portion of the delivery state in Fig. 9A.
- [0026]** Fig. 10B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 10A.
- [0027]** Fig. 11A illustrates a side view of portions of the drug delivery device in Fig. 3A, namely the drive mechanism and guard, in a post-delivery state. The rotatable member in Fig. 8A is illustrated as being semi-transparent.
- [0028]** Fig. 11B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 11A.
- [0029]** Fig. 12A is an exploded assembly view of another embodiment of a drug delivery device.
- [0030]** Fig. 12B is an exploded assembly view of the drive mechanism in Fig. 12A.
- [0031]** Fig. 13 is a perspective view of the releaser in Fig. 12B.
- [0032]** Figs. 14A and 14B are perspective views of the rotatable member in Fig. 12B.
- [0033]** Fig. 15 is a perspective view of the transmitter in Fig. 12B.
- [0034]** Fig. 16A illustrates a side view of portions of the drug delivery device in Fig. 12A, namely the drive mechanism, guard, container holder, and rear end cap, in the storage state.
- [0035]** Fig. 16B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 16A.
- [0036]** Fig. 17A illustrates a side view of portions of the drug delivery device in Fig. 12A, namely the drive mechanism, guard, container holder, and rear end cap, in an initial portion of the delivery state.

[0037] Fig. 17B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 17A.

[0038] Fig. 18A illustrates a side view of portions of the drug delivery device in Fig. 12A, namely the drive mechanism, guard, container holder, and rear end cap, in a portion of the delivery state after the portion of the delivery state in Fig. 17A.

[0039] Fig. 18B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 18A.

[0040] Fig. 19 illustrates a side view of portions of the drug delivery device in Fig. 12A, namely the drive mechanism and guard, in a portion of the delivery state after the portion of the delivery state in Fig. 18A. The rotatable member of the drive mechanism is depicted as semi-transparent in Fig. 19.

[0041] Fig. 20A illustrates a side view of portions of the drug delivery device in Fig. 12A, namely the drive mechanism, guard, container holder, and rear end cap, in a post-delivery state.

[0042] Fig. 20B illustrates a side view of the plunger guide and, in dashed lines, a portion of the rotatable member, in the state shown in Fig. 20A.

[0043] Fig. 21A is an exploded assembly view of another embodiment of a drug delivery device.

[0044] Fig. 21B is an exploded assembly view of the drive mechanism in Fig. 21A.

[0045] Figs. 22A and 22B are perspective views of the rotatable member in Fig. 21B.

[0046] Fig. 23 is a cutaway view of a portion of the housing in Fig. 21A.

[0047] Fig. 24 illustrates a side view of portions of the drug delivery device in Fig. 21A, namely the drive mechanism, guard, the rotatable member engagement member of the housing, and container holder, in the storage state.

[0048] Fig. 25 illustrates a side view of portions of the drug delivery device in Fig. 21A, namely the drive mechanism, guard, the rotatable member engagement member of the housing, and container holder, in an initial portion of the delivery state.

[0049] Fig. 26 illustrates a side view of portions of the drug delivery device in Fig. 21A, namely the drive mechanism, guard, the rotatable member engagement member of the housing, and container holder, in a portion of the delivery state after the initial portion of the delivery state in Fig. 25.

[0050] Fig. 27 illustrates a side view of portions of the drug delivery device in Fig. 21A, namely the drive mechanism, guard, the rotatable member engagement member of the housing, and container holder, in an initial portion of the post-delivery state.

[0051] Fig. 28 illustrates a side view of portions of the drug delivery device in Fig. 21A, namely the drive mechanism, guard, the rotatable member engagement member of the housing, and container holder, in a portion of the post-delivery state after the initial portion of the post-delivery state in Fig. 27.

DETAILED DESCRIPTION

[0052] The present disclosure generally pertains to drug delivery devices operable by a user for administering a drug, or in the case where the user is the patient, self-administering a drug. Various features are disclosed for simplifying, automating, and/or facilitating certain aspects of injecting a drug, such as those utilized in autoinjectors, on-body injectors, and/or other automatic or partially automatic drug delivery devices (collectively autoinjectors or auto-injectors). For example, these features may include automatically covering a needle in a pre-delivery and/or post-delivery state, automatically activating a drive mechanism, automatically indicating to the user that drug delivery is complete, among other features. One or more of these features may be powered by one or more springs which a user may be required to compress or otherwise charge by pressing a guard against an injection site, for example, to expose a distal end of the needle for insertion into the injection site. The present disclosure provides various configurations and arrangements which alleviate the user from having to maintain, or aid in maintaining, one or more of these springs in a compressed or charged state before, during, and/or after drug delivery. For example, these configurations and arrangements may reduce or eliminate an amount of force that the user must apply to the drug delivery device to hold the guard in a retracted position during drug delivery. As a result, operating the drug delivery device may be simplified and made more reliable for the user. Furthermore, the user may be less likely to remove the needle from the injection site in the midst of drug delivery due to, for example, a sensation that the guard wants to push off of the skin. The chances of successful and complete delivery of the drug are therefore increased. Moreover, a reduced holding force requirement may decrease the likelihood that the user inadvertently moves the needle laterally with respect to the injection site and potentially causes discomfort to the patient. These and other advantages will be apparent to one of ordinary skill in the art reviewing the present disclosure.

[0053] Figs. 1-3 illustrate several views of an embodiment 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 biologics such as peptides, peptibodies, or antibodies. The drug may be in a fluid or liquid form, although the present disclosure is not limited to a particular state.

[0054] Various implementations and configurations of the drug delivery device 10 are possible. The present embodiment of the drug delivery device 10 is 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 is 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 example drug delivery devices shown in the figures 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, but may also or alternatively be suitable for other drug delivery devices and/or configurations.

[0055] 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 storage state,

a pre-delivery state, a delivery or dosing state, and a post-delivery state, although fewer or more states are also possible. For example, each state may have several sub-states or stages. The storage state may correspond to the configuration of the drug delivery device 10 in Fig. 1A, where the delivery device 10 includes a removable cap 19 in a storage position. In some embodiments, the storage state may exist in the time between when the drug delivery device 10 leaves a manufacturing facility and when a patient or other user removes the removable cap 19. Additionally or alternatively, the storage state may correspond may exist in the time between when the user removes the drug delivery device 10 from secondary packaging and when the user removes the removable cap 19 and may be referred to as the out-of-pack state. The pre-delivery state may correspond to the configuration(s) of the drug delivery device 10 after the removable cap has been removed but prior to activation of a drive mechanism by the user. This may include the moments in time after the user has removed the removable cap, including while the user is first positioning the drug delivery device 10 against the injection site, but before drug delivery has begun, as seen in Fig. 1B. The delivery state may correspond to the configuration(s) of the drug delivery device 10 while drug delivery, also referred to herein as dosing, is in progress, as depicted in Fig. 1C. The delivery state may additionally include configuration(s) of the drug delivery device 10 when a plunger biasing member has been released but before a plunger has begun expelling drug from the drug delivery device 10. The post-delivery state may correspond to the configuration(s) of the drug delivery device 10 after drug delivery is complete and/or when a stopper is arranged in an end-of-delivery or end-of-dose position in a drug storage container.

[0056] As shown in Figs. 1-3, the drug delivery device 10 may include 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 shape, such as a cylindrical shape, and extend along a longitudinal axis A between a proximal end and a distal end. An opening 14 (Fig. 2) may be formed in the distal end to permit an insertion end 28 of a delivery member 16 to extend outside of the housing 12. A transparent or semi-transparent inspection window 17 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 at the distal end of the device prior to use of the drug delivery device 10, and, in some embodiments, may include a gripper 13 (Fig. 3A) configured to assist with removing a removable 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 removable sterile barrier 21 to pull the removable 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 removable sterile barrier 21 from the delivery member 16.

[0057] In some embodiments, the housing 12 may include two separate and interconnected structures: a rear end cap 23 (e.g., a rear cover) 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, such as a two-piece tubular housing having front and rear portions. 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 (Fig. 3B). 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 and tubular housing in a single component.

[0058] The drug storage container 20 is disposed within an interior space of the housing 12 and is configured to contain a drug. 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.

[0059] 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 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 drug storage container 20 such that it can move in a distal direction along the longitudinal axis A between a 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 an axial gap. Upon activation of a drive mechanism 30, the plunger 26 moves in the distal direction to close the axial 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-delivery or end-of-delivery position, and may correspond to when delivery of the drug 22 to the patient is complete or substantially complete.

[0060] 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.

[0061] The delivery member 16 is connected or operable to be connected in fluid communication with the reservoir 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 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.

[0062] In one embodiment, the drug storage container 20 may be a pre-filled syringe and have 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.

[0063] 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 may extend permanently through the opening 14 in the housing 12 in the storage, pre-delivery, delivery, and post-delivery states. For example, as shown in Fig. 2, the insertion end 28 of the delivery member 16 extends beyond a distal end of the housing 12 that defines the opening 14 in the delivery state. In certain other states, including the storage state shown in Fig. 2, the insertion end 28 of the delivery member 16 may extend beyond the distal end of the housing 12 but is covered or protected by the removable cap 19, the sterile barrier 21, and/or a guard 32 that surrounds the delivery member 16 and protects against or reduces the likelihood of unintended or premature needle stick.

[0064] The drug delivery device 10 may also include a container holder 31 configured to secure the drug storage container 20 with respect to the housing 12, such as by preventing distal movement of the drug storage container 20 during actuation of the plunger 26. The container holder 31 may have a hollow and generally cylindrical or tubular shape centered about the longitudinal axis A, and the drug storage container 20 may be disposed partially or entirely within the container holder 31. A distal end of the container holder 31 may include one or more inwardly protruding flanges 33 abutting against a shoulder portion of the drug storage container 20, thereby preventing distal movement of the drug storage container 20 during actuation of the plunger 26. In some embodiments, each of the flanges 33 may include an arcuate, sloped surface 33a that substantially matches an arcuate shape of a shoulder portion of the drug storage container 20. As a more specific example, when the drug storage container 20 is inserted within the container holder 31, the flanges 33 may cooperate to support the shoulder portion of the drug storage container 20 to limit or prevent travel of the drug storage container 20 in the distal direction. The housing 12 may include a plurality of lock slots that each receive respective one of the flanges 33 of the container holder 31 to prevent and/or restrict relative movement between the respective components 12 and 31. As a result, when fully assembled the storage container 20, the container holder 31, and the housing 12 are all substantially or completely fixed with respect to each other.

[0065] 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 32 moveably disposed at or near the

distal end of the housing 12 adjacent to the opening 14. The guard 32 may have a hollow and generally tubular shaped or cylindrical portion 32a centered about the longitudinal axis A. The guard 32 may also have a pair of longitudinally extending arms 32b and 32c which extend in the proximal direction from the cylindrical portion 32a. The guard 32 may further include a distal end 32d that may generally include the cylindrical portion 32a and a proximal end 32e that may be defined by the longitudinally extending arms 32b and 32c. The longitudinally extending arms 32b and 32c may be substantially or completely received within the housing 12 such that no part thereof extends from the housing 12. The cylindrical portion 32a may be at least partially and/or selectively received within the housing 12. For example, the guard 32 may be configured to move relative to the housing 12 such that portions of the guard 32 are received within the housing 12 in some states and are extending from the housing 12 in other states.

[0066] The guard 32 may be configured to move along the longitudinal axis A, having at least a first axial position or extended position with respect to the housing 12 and a second axial position or retracted position with respect to the housing 12. Additional axial position(s) of the guard 32 with respect to the housing 12 are possible. The first axial position of the guard 32 may be distal to the second axial position of the guard 32. The guard 32 may be positioned in the first axial or extended position prior to the delivery state including, for example, during the storage state and/or the pre-delivery state, and/or after the delivery state, including, for example, during the post-delivery state. The guard 32 may be positioned in the second axial or retracted position during, for example, a portion of or the entirety of the delivery state. In some embodiments, the guard 32 may be in the pre-delivery state when moving from the first axial position to the second axial position.

[0067] In the first axial position, a length X (see Fig. 1B) of the cylindrical portion 32a of the guard 32 may extend out through the opening 14 in the housing 12 such that at least this portion of the guard 32 is outside of the housing 12. In the second axial position, a length Y (see Fig. 1C) of the cylindrical portion 32a may extend out through the opening 14 in the housing 12, wherein X is a value greater than Y. The length X may be any suitable number including, for example, 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. Fig. 1B illustrates an example of a pre-delivery state where the guard 32 is in the first axial or extended position and the length of the exposed portion X of the guard 32 may be approximately 5 mm to 11 mm. Fig. 1C illustrates an example of a delivery state where the guard 32 is in the second axial or retracted position and the length of the exposed portion Y of the guard 32 is approximately 0 mm to 2 mm (such that the distal end 32d of the guard 32 is flush or substantially flush with the opening 14 of the housing 12). In some embodiments, the distance Y is greater than zero (e.g., 1 mm) to help ensure the device 10 is able to be activated before the guard is flush or substantially flush with the housing 12.

[0068] The guard 32 may also be configured to move in the opposite direction, namely from the second axial position to the first axial position. When moving from the first axial position to the second axial position, the guard 32 may translate linearly in the proximal direction along the longitudinal axis A; and when moving from the second axial position to the first axial position, the guard 32 may translate linearly in the distal direction along the longitudinal axis A. In at least the first axial position, the guard 32 may extend beyond and surround the insertion end 28 of the delivery member 16. In embodiments where the insertion end 28 of the delivery member 16 extends through the opening 14 in the housing 12 in the pre-delivery and/or storage states, moving the guard 32 from the first axial position to the second axial position, e.g., by pressing the distal end of the guard 32 against the patient's skin 5 at the injection site, may result in the insertion end 28 of the delivery member 16 being inserted into the patient's skin 5.

[0069] During the delivery state, the guard 32 may remain stationary with respect to the user's skin 5 while the housing 12 and/or component(s) disposed therein are moving with respect to the guard 32 and the skin 5. Nonetheless, this disclosure refers to moving, retracting, translating, and depressing the guard 32. These references and descriptions may be considered to refer to relative movement between the guard 32 and the housing 12, regardless of which component (guard 32 or housing 12) is moving with respect to the user's skin 5.

[0070] In some embodiments, the guard 32 may be rotationally fixed or rotationally restricted relative to the housing 12. Therefore, although the guard 32 may be able to translate linearly with respect to the housing 12, the guard 32 may be substantially or completely prevented from rotating with respect to the housing 12.

[0071] In alternative embodiments, the drug storage container 20 may be moveably coupled with the housing 12 such that the drug storage container 20 is able to move relative to the housing 12 during operation of the drug delivery device 10. In certain such alternative embodiments, the insertion end 28 of the delivery member 16 may be retracted within the opening 14 in the housing 12 in the pre-delivery state. Subsequently, during operation of the injection device 10, the insertion end 28 of the delivery member 16 may be deployed through the opening 14 in the housing 12 for insertion into the patient. This motion may, in some embodiments, be the result of the drug storage container 20 having been driven in the distal direction relative to the housing 12.

[0072] 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 the stored energy to drive the plunger 26 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, or a combination of mechanical,

electrical, and/or chemical potential energies. 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.

[0073] As illustrated in Fig. 3B, in some embodiments, 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, a releaser member 52, a plunger guide 60, a proximal biasing member 35, and a rotatable member 37. The plunger biasing member 50 may include 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 non-energized state, and, as a consequence, the plunger biasing member 50 may exert a distally directed biasing force on the plunger 26 and a proximally directed biasing force on another component(s), which, in some embodiments, may include the releaser member 52. When released, the plunger biasing member 50 may try to expand to its natural axial length, and, as a consequence, push the plunger 26 in the distal direction, and, in some embodiments, depend on the state of operation, push the releaser member 52 in the proximal direction.

[0074] The plunger 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 guide 60 may be larger than an outer diameter or other outer dimension of a distal end of the plunger guide 60. The plunger guide 60 may be fixedly coupled with the housing 12 such that the plunger guide 60 is substantially and/or generally immovable with respect to the housing 12, or is at least rotationally fixed or locked with respect to the housing 12. For example, the plunger guide 60 may include a lock tab or other protrusion that is sized, shaped, and/or aligned to be received within a lock key or other mating structure formed in the housing 12. As another example, the plunger guide 60 and housing 12 each may include a pair of respective components that cooperate to prevent relative rotation between the plunger guide 60 and the housing 12, such that the plunger guide 60 is rotationally fixed or locked with respect to the housing 12. Additionally or alternatively, annular ridges formed on an outer surface of the plunger guide 60 may form a friction fit with the inner surface of the housing 12 to resist or prevent rotation between the plunger guide 60 and housing 12. Additional features and functions of the plunger guide 60 are discussed below.

[0075] In some embodiments, at least a portion of releaser member 52 may be positioned radially between the plunger 26 and the plunger guide 60, such that the plunger 26 may be disposed at least partially within the releaser member 52 and the releaser member 52 may be disposed at least partially within the plunger guide 60, as seen in Figs. 2 and 3A. In other embodiments, at least a portion of the plunger guide may be positioned radially between the plunger and the releaser member, such that the plunger may be disposed at least partially within the plunger guide and the plunger guide may be disposed at least partially within the releaser member.

[0076] The plunger 26, as seen in Fig. 3B, may have a hollow and generally cylindrical or tubular shape. The plunger 26 may include an annular wall 39 with an outer surface 41 and an inner surface 43. The inner surface 43 may define an interior space sized to receive a plunger biasing member 50 therein. The annular wall 39 may be made of any suitable material, such as metal or plastic. It may be advantageous for the annular wall 39 to be made of metal, such as steel or aluminum, for the purpose of, for example, minimizing the thickness of the annular wall 39.

[0077] As described below in more detail, the plunger 26 may be configured to selectively rotate relative to the housing 12 and translate linearly relative to the housing 12 during operation of the drug delivery device 10 including, for example, during the delivery state.

[0078] The plunger 26 may be constructed of multiple, interconnected pieces, or alternatively, have a one-piece construction. In some embodiments, the plunger 26 is constructed of three separate and interconnected structures: a top ring 45 defining a proximal end of the plunger 26; a base 47 defining a distal end of the plunger 26; and a hollow rod 46 positioned between and rigidly connecting the top ring 45 and the base 47. The positions of the top ring 45, hollow rod 46, and base 47 may be fixed relative to each other such that these components are immovable relative to each other. The top ring 45, hollow rod 46, and base 47 may each have an annular construction and may be centered about the longitudinal axis A. The top ring 45 and hollow rod 46 may each have a respective central opening extending from end to end of the component to define an axial chamber; whereas, the base 47 may have a central opening extending through the proximal end of the base 47 but which is closed off at the distal end of the base 47. The closed off end of the base 47 may define seat or abutment surface for the plunger biasing member 50. In alternative embodiments, the central opening may extend through the base 47 from end to end. In such alternative embodiments, an inner diameter of the central opening of the base 47 may be smaller than an outer diameter of the plunger biasing member 50 such that the base 47 retains a distal end of the plunger biasing member 50 within the plunger 26. When the drive mechanism 30 is activated, the base 47 may be the portion of the plunger 26 that comes into contact with the stopper 24 to push the stopper 24 in the distal direction.

[0079] The top ring 45 may include one or more flanges or protrusions 48a and 48b which extend radially outwardly from a central portion of the top ring 45. The flanges 48a and 48b may include, respectively, distally facing camming surfaces 49a and 49b (e.g., ramps). As described below in more detail, each of the distally facing camming surfaces 49a and 49b may interact with a counterpart proximally facing camming surface on the plunger guide 60 in order to release the plunger biasing member 50. In some embodiments, the distally facing camming surfaces 49a and 49b each may be arranged at an angle or slope relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A.

[0080] In some embodiments, the top ring 45 and/or the base 47 may be constructed of a different material than the hollow rod 46. In some embodiments, the top ring 45 and/or the base 47 may be

constructed of plastic whereas the hollow rod 46 may be constructed of metal. So configured, the plastic material used for the top ring 45 may facilitate the camming action described below by providing a relatively low coefficient of friction, the plastic material used for the base 47 may help absorb or attenuate any shock or vibrations associated with base 47 striking the stopper 24. The metal material used for the hollow rod 46 may provide sufficient rigidity to avoid buckling under the biasing force exerted by the plunger biasing member 50. In alternative embodiments, the top ring 45, hollow rod 46, and/or base 47 may be made of the same material, including, for example, metal or plastic. In certain such embodiments, the top ring 45, hollow rod 46, and base 47 may be integrally formed in one piece so as to define single, monolithic structure.

[0081] 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 base 47 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 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 of the plunger biasing member seat 38. The plunger biasing member seat 38 may be fixedly attached to the tubular housing 25 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. However, in the embodiment shown in the figures, neither the release of the plunger biasing member 50 nor any other biasing members cause the delivery member 16 to drive downward with respect to the housing 12. On the contrary, the drug product container 20, and as a result the delivery member 16, is substantially or completely fixedly coupled with respect to the housing 12. The delivery member 16 is driven into the patient's skin 5 by inertial force generated by a downward force by the patient (or a health care provider or other person administering the dose).

[0082] As illustrated in Fig. 2, the rotatable member 37 may be positioned proximal to the guard 32, and the proximal biasing member 35 may be positioned proximal to the rotatable member 37. The rotatable member 37 may be a separate structure from the guard 32 and, in at least some embodiments, may generally function as and/or take the form of a guard extension or guard extender. The rotatable member 37 may have a hollow and generally cylindrical or tubular shape centered about the longitudinal axis A. As

an example, the rotatable member 37 may include a generally cylindrical body 37a. The rotatable member 37 may also include a groove 37b for receiving, supporting, and/or retaining a distal portion of the proximal biasing member 35. Furthermore, depending on the state or stage of operation of the drug delivery device 10, the rotatable member 37 may be configured to move in a linear direction along the longitudinal axis A relative to the housing 12 and/or rotate about the longitudinal axis A relative to the housing 12, as described below in more detail.

[0083] Prior to the delivery state, including, for example, in the storage and/or pre-delivery states, the rotatable member 37 may be configured to move linearly, including in the proximal direction, relative to the housing 12 along the longitudinal axis A but may be prevented from rotating relative to the housing 12 about the longitudinal axis A. To achieve this effect, in some embodiments the rotatable member 37 may cooperate with the plunger guide 60 to prevent relative rotational movement between, but permit relative axial movement between, the rotatable member 37 and the plunger guide 60 prior to the delivery state. As a result, and because the plunger guide 60 is fixedly coupled with the housing 12, the rotatable member 37 may be rotationally fixed to the housing 12 through the plunger guide 60. For example, as illustrated in Figs. 4A and 4B an outer portion of the plunger guide 60 may include a first rotatable member engagement member 60a and an inner portion of the rotatable member 37 may include a plunger guide engagement member 37c. The first rotatable member engagement member 60a of the plunger guide 60 may include a protrusion (e.g., a longitudinally extending ridge or spline) which extends radially outwardly, is disposed near a distal end of the plunger guide 60, and has at least one surface that is parallel or substantially parallel to the longitudinal axis A. The plunger guide engagement member 37c of the rotatable member 37 may include a protrusion which extends radially inwardly and is disposed near a proximal end of the rotatable member 37. The first rotatable member engagement member 60a may be configured to engage the plunger guide engagement member 37c to prevent the rotatable member 37 from rotating with respect to the plunger guide 60 and housing 12, while allowing the rotatable member 37 to move linearly with respect to the plunger guide 60 and housing 12. As an example, the plunger guide engagement member 37c may slide against the first rotatable member engagement member 60a when the rotatable member 37 moves linearly with respect to the plunger guide 60 as a result of the user pushing the guard 32 in the proximal direction to activate the drive mechanism 30 and/or uncover the insertion end 28 of the delivery member 16. Additionally or alternatively, the rotatable member 37 may include an anti-rotation feature that mates with a corresponding feature disposed on the inner surface of the housing 12.

[0084] During at least an initial portion of the delivery state, the rotatable member 37 may be configured to rotate jointly together with the releaser member 52, with respect to the plunger guide 60 and the housing 12. In some embodiments, to achieve this effect, an outer portion of the releaser member 52 may include a rotatable member engagement member 52a and an inner portion of the rotatable member 37 may include releaser member engagement member 37d. The rotatable member engagement member 52a of the

releaser member 52 may include a protrusion which extends radially outwardly and is disposed near a distal end of the releaser member 52. The releaser member engagement member 37d may include a protrusion which extends radially inwardly and is disposed near a distal end of the rotatable member 37. The rotatable member engagement member 52a of the releaser member 52 may be configured to engage the releaser member engagement member 37d of the rotatable member 37 such that, when the rotatable member 37 is not rotationally fixed with the plunger guide 60 due to the plunger guide engagement member 37c of the rotatable member 37 disengaging from the first rotatable member engagement member 60a of the plunger guide 60, rotation of the releaser member 52 (e.g., caused by expansion of the plunger biasing member 50) causes the rotatable member 37 to rotate (together with the releaser member 52) about the longitudinal axis A, for example, from a first rotational position to a second rotational position. Further features and functions of the rotatable member 37 are discussed below.

[0085] As illustrated in Fig. 2, in some embodiments, the proximal biasing member 35 may be positioned between and in contact with the rotatable member 37 and the plunger guide 60. The proximal biasing member 35 may be configured to bias (e.g., urge) the rotatable member 37 in the distal direction and, depending on the state of the drug delivery device 10, bias the guard 32, via the rotatable member 37, in the distal direction. In other embodiments, such as those illustrated in Figs. 12-28, the proximal biasing member may be positioned between and in contact with the rotatable member and the releaser member. Furthermore, in some embodiments, proximal biasing member may have a diameter that is larger than a diameter of the plunger biasing member and/or may be disposed radially outwardly of at least a portion of the plunger biasing member.

[0086] The proximal biasing member 35 may include a compression spring (e.g., a helical compression spring). In some embodiments, the proximal biasing member 35 may be initially (e.g., in the storage state) retained in an energized state; whereas, in other embodiments, the proximal biasing member 35 may be initially (e.g., in the storage state) in a non-energized or natural state. In the energized state, the proximal biasing member 35 may be compressed such that its axial length is shorter than it would be in the non-energized state or natural state.

[0087] When the guard 32 moves the rotatable member 37 in the proximal direction during, for example, the pre-delivery state, the proximal biasing member 35 may be compressed in the axial direction between the rotatable member 37 and the plunger guide 60 (or the releaser member 52 if a proximal end of the proximal biasing member 35 is seated against the releaser member 52 instead of the plunger guide 60). Compressing the proximal biasing member 35 may require the user to apply a force to the drug delivery device 10, for example, by pushing the guard 32 against the injection site to cause the guard 32 to move in the proximal direction from the first axial position toward the second axial position.

[0088] During operation of the drug delivery device 10, a user may cause the guard 32 to translate with respect to the housing 12 in the proximal direction by pressing the guard 32 against the injection site. In

doing so, the guard 32 will move towards the rotatable member 37 and close the axial gap therebetween. Once the axial gap is eliminated, the guard 32 and the rotatable member 37 may move jointly in the proximal direction until, for example, the guard 32 reaches the second axial position. This motion may compress the proximal biasing member 35. In some embodiments, when drug delivery is complete and the drug delivery device 10 is lifted off of the injection site, the proximal biasing member 35 may expand from its compressed or energized state to push, or assist in pushing, the guard 32 (via the rotatable member 37) in the distal direction. This motion and/or a distally directed biasing force from a distal biasing member 51 may return the guard 32 to the first axial position or extended position, which has the effect of covering the insertion end 28 of the delivery member 16. In other embodiments (including the embodiment illustrated in Figs. 1-11), when drug delivery is complete and the drug delivery device 10 is lifted off of the injection site, the proximal biasing member 35 may not push the guard 32 in the distal direction, and, instead, the distal biasing member 51 may be solely responsible for pushing the guard 32 in the distal direction to the first axial position or extended position.

[0089] After drug delivery is complete and the guard 32 has been re-deployed to the extended position, it may be desirable to lock the guard 32 in the extended position to prevent subsequent user contact with the insertion end 28 of the delivery member 16 and/or to prevent re-use of the drug delivery device 10.

Pursuant to these ends, at least some embodiments of the drug delivery device 10 may include a lock ring 40 configured to selectively rotate, depending on the axial position of the guard 32, in order to lock the guard 32 in the extended position once the guard 32 has moved from the retracted position to the extended position. The lock ring 40 may be centered and rotate about the longitudinal axis A. A proximal end of the lock ring 40 may be in contact with the container holder 31 and the distal end of the lock ring 40 may be disposed at least partially within the guard 32. The distal biasing member 51 may be positioned in the axial direction between a distally facing surface of the lock ring 40 and a proximally facing surface of the guard 32. The distal biasing member 51 may initially be in a compressed or energized state such that it biases the lock ring 40 and the guard 32 away from each other. As such, the distal biasing member 51 may exert a biasing force urging the guard 32 toward the extended position, as well as exert a biasing force urging the proximal end of the lock ring 40 against the container holder 31. In some embodiments, the distal biasing member 51 may include a compression spring (e.g., a helical compression spring). In some embodiments, rotation of the lock ring 40 may be achieved by a camming arrangement between the lock ring 40 and the container holder 31. In alternative embodiments, the lock ring 40 may be omitted and/or the rotatable member 37 may be configured to lock the guard 32 in the extended position once the guard 32 has moved from the retracted position to the extended position.

[0090] 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 radially positioned between the plunger guide 60 and the plunger 26. As also illustrated in Fig. 2, the releaser

member 52 may be radially positioned between the rotatable member 37 and the plunger 26. Furthermore, in some embodiments, a proximal end of the releaser member 52 may be coupled with the plunger biasing member seat 38 such that the plunger biasing member 50 may be configured to bias the releaser member 52 in the proximal direction. Generally, the releaser member 52 may be configured to: (1) operably couple the guard 32 and the plunger 26 in an activation sequence; and (2) generate an audible signal indicating the end of drug delivery. So configured, the releaser member 52 is exploited to perform two separate functions, and thus reduces the number of moving parts required by the drug delivery device 10.

[0091] 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 state or 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; whereas later rotation of the releaser member 52 associated with generation of the end-of-delivery signal may be powered by the plunger biasing member 50 and/or guard biasing member 35. In the embodiment illustrated in Figs. 1-11, rotation of the releaser member 52 associated with the generation of the end-of-delivery signal may be powered solely by the proximal biasing member 50; whereas, in the embodiments illustrated in Figs. 12-28, rotation of the releaser member 52 associated with the generation of the end-of-delivery signal may be powered solely by the proximal 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.

[0092] In some embodiments, an ability of the releaser member 52 to rotate about the longitudinal axis A may be regulated or controlled by the engagement or lack of engagement between the rotatable member 37 and the plunger guide 60. For example, in the storage and/or pre-delivery states, when the plunger guide engagement member 37c of the rotatable member 37 engages the first rotatable member engagement member 60a of the plunger guide 60, the releaser member 52 may be unable to rotate about the longitudinal axis A. That is because the mentioned engagement may prevent the rotatable member 37 from rotating, and, consequently, the rotatable member 37 may prevent the releaser member 52 from rotating, due to the engagement between the releaser member engagement member 37d of the rotatable member 37 and the rotatable member engagement member 52a of the releaser member 52.

[0093] If the releaser member 52 is unable rotate, the plunger 26 may also be unable to rotate due to the outwardly extending flanges 48a and 48b of the top ring 45 of the plunger 26 being received in respective longitudinally extending openings or slots 52b and 52c formed in the annular wall of the releaser member 52. If the flanges 48a and 48b on the plunger 26 cannot rotate, then they cannot slide into respective longitudinally extending recesses 60b and 60c (e.g., grooves, depressions, slots, and/or channels) formed in an inner surface of the plunger guide 60. If the flanges 48a and 48b cannot move in this manner, then the plunger 26 also cannot move. If the plunger 26 cannot move, the plunger biasing member 50 cannot

expand to de-energize. Thus, the releaser member 52 retains the plunger biasing member 50 in the energized state until the rotatable member 37 moves to an axial position where the plunger guide engagement member 37c of the rotatable member 37 disengages from the first rotatable member engagement member 60a of the plunger guide 60, thereby allowing the rotatable member 37 and releaser member 52 to jointly rotate.

[0094] The rotation of the rotatable member 37 and releaser member 52 may be powered by the plunger biasing member 50 via a camming arrangement, as will now be further described. In the storage and/or pre-delivery states, the distally facing camming surface 49a and 49b of the flanges 48a and 48b of the top ring 45 of the plunger 26 may abut against respective proximally facing camming surfaces 60d and 60e (e.g., ramps) formed by an inner portion of the plunger guide 60, such that the plunger 26 is restrained from axial travel due to this interaction. The camming surfaces 49a, 49b, 60d, and/or 60e each may have a slope to promote relative movement of the top ring 45 and the plunger guide 60. The slope(s) of the camming surfaces 49a, 49b, 60d, and/or 60e may translate or convert at least a portion the axial biasing force from the plunger biasing member 50 into a force in a transverse direction with respect to the longitudinal axis A, thereby urging the top ring 45 and the remainder of the plunger 26 to rotate about the longitudinal axis A. However, the releaser member 52 may prevent or resist rotational movement between the releaser member 52 and the plunger 26 while the outwardly extending flanges 48a and 48b of the top ring 45 of the plunger 26 are received in the respective longitudinally extending openings 52b and 52c formed in the annular wall of the releaser member 52. As a result, as long as the rotatable member 37 rotationally locks the releaser member 52, then the top ring 45 may remain rotationally locked by the longitudinally extending openings 52b and 52c of the releaser member 52 and axially locked by the proximally facing camming surfaces 60d and 60e of the plunger guide 60.

[0095] When the rotatable member 37 translates in the proximal direction to a position where the plunger guide engagement member 37c of the rotatable member 37 no longer engages the first rotatable member engagement member 60a of the plunger guide 60, the rotatable member 37 and releaser member 52 are no longer rotationally locked with the plunger guide 60. As a result, the plunger biasing member 50 may begin to expand in the distal direction, pushing the distally facing camming surface 49a and 49b of flanges 48a and 48b of the top ring 45 of the plunger 26 to slide against the respective proximally facing camming surfaces 60d and 60e formed by an inner portion of the plunger guide 60. The resulting camming action at this sliding interface may cause the plunger 26 to rotate, which, in turn, may cause the releaser member 52 to jointly rotate, due to the outwardly extending flanges 48a and 48b of the top ring 45 of the plunger 26 being received in the respective longitudinally extending openings 52b and 52c formed in the annular wall of the releaser member 52. The rotatable member 37 may rotate jointly with the releaser member 52 at this time due the engagement between the releaser member engagement member 37d of the rotatable member 37 and the rotatable member engagement member 52a of the releaser member 52.

[0096] Joint rotation of the releaser member 52, rotatable member 37, and plunger 26 may continue until the distally facing camming surfaces 49a and 49b of the plunger 26 clear the ends of the respective proximally facing camming surfaces 60d and 60e of the plunger guide 60 and move into respective longitudinally extending recesses 60b and 60c of the plunger guide 60. The longitudinally extending recesses 60b and 60c may not inhibit linear movement of the plunger 26. As consequence, the plunger 26 may be driven by the expanding plunger biasing member 50 to translate linearly in the distal direction, for example, in a downward stroke. As a consequence, the plunger 26 may come into contact with the stopper 24 (if it is not already in contact with the stopper 24) and thereafter push the stopper 24 in the distal direction to expel the drug 22 from the drug storage container 20 through the delivery member 16 and out of the insertion end 28 of the delivery member 16 into the patient's tissue. Drug delivery may carry on until the stopper 24 reaches the end-of-delivery position. Here, the stopper 24 may abut against a proximally facing portion of the interior surface 15 of the wall of the drug storage container 20. As a result, the plunger 26 may cease moving in the distal direction.

[0097] During at least an initial portion of the distal movement of the plunger 26, the flanges 48a and 48b of the top ring 45 of the plunger 26 may be traveling along both the longitudinally extending openings 52b and 52c of the releaser member 52 and the longitudinally extending recesses 60b and 60c of the plunger guide 60, thereby preventing rotation between any of the three components. However, as the plunger 26 nears the end-of-delivery position, the top ring 45 may clear the distal end of the plunger guide 60 and thus the plunger guide 60 may no longer restrict or prevent rotation of the plunger 26 and/or releaser member 52. As a result, the plunger biasing member 50 may begin to expand in the proximal direction, pushing a proximally facing camming surface of the releaser member 52 to slide against a distally facing surface of the plunger guide 60. The resulting camming action at this sliding interface may cause the releaser member 52 to rotate and move linearly in the proximal direction until a surface (e.g., a proximally facing surface) of the releaser member 52 strikes a surface (e.g., a distally facing surface) of another component such as the plunger guide 60 to generate an end-of-delivery or end-of-dose click or other audible signal.

[0098] Once the patient and/or health care provider hears the end-of-delivery signal, he/she/they may be notified that the dose is complete. In some embodiments, the user may be informed of the significance of the audible signal by way of instructions provided with the drug delivery device 10. In some embodiments, these instructions may take the form of an Instructions for Use (IFU) pamphlet packaged together with the drug delivery device 10. In some embodiments, the user may obtain additional confirmation that drug delivery is complete by watching movement of the stopper 24 and/or plunger 26 through the window 17. In some embodiments, the audible signal may be accompanied by a vibration or other tactile feedback or tactile signal produced as a result of the releaser member 52 striking the plunger guide 60. The audible notification may be in the form of a click or slap sound, or any other suitable audible signal that is

perceptible to the user. The audible signal may be generated simultaneously, or substantially simultaneously, with the stopper 24 reaching the end-of-delivery position.

[0099] In any case, once the user receives some assurance that drug delivery is complete, the user may then lift the drug delivery device 10 off of the injection site. With nothing to resist it, the distal biasing member 51, which may have been previously compressed due to movement of the guard 32 from the first axial or extended position to the second axial or retracted position, may push the guard 32 from the second axial or retracted position to the first axial or extended position to cover the insertion end 28 of the delivery member 16. In some embodiments, the distal biasing member 51 may move the guard 32 from the second axial or retracted position to the first axial or extended position independent of (e.g., without the assistance of) the proximal biasing member 35. In some embodiments, movement of the guard 32 from the second axial or retracted position to the first axial or extended position may cause the lock ring 40 to rotate to a position where it prevents subsequent retraction of the guard 32.

[0100] Generally, the drug delivery device 10 may be configured so as to eliminate or reduce an amount of a downward or distally directed force that the user must apply to the drug delivery device 10 in order to hold the insertion end 28 of the delivery member 16 at an inserted position in the patient's tissue during, for example, the delivery state. As described above, in order to move the guard 32 from the first axial or extend position to the second axial or retracted position to uncover the insertion end 28 of the delivery member 16, the user may be required to press the guard 32 against the skin at the injection site with sufficient force to overcome the distally directed biasing force(s) of the distal biasing member 51 and/or the proximal biasing member 35 and thereby compress in the distal biasing member 51 and/or the proximal biasing member 35. In their respective compressed states, the distal biasing member 51 and/or the proximal biasing member 35 may continue to exert their distally directed biasing force(s) against whichever component(s) are holding them in their respective compressed states. If the guard 32 is one of these component(s), the user may be required to counteract the distally directed biasing force(s) of the biasing members 51 and/or 35 in order to hold the guard 32 in the second axial or retracted position.

[0101] At least the proximal biasing member 35 may be configured to selectively (e.g., intermittently) bias the guard 32 in the distal direction. Whether or not the proximal biasing member 35 biases the guard 32 in the distal direction may depend on, for example, the state or sub-state of operation of the drug delivery device 10. As an example, the proximal biasing member 35 may be configured to bias the guard 32 in the distal direction during at least a portion of the pre-delivery state (e.g., during at least a portion of the movement of the guard 32 from the first axial or extended position toward the second axial or retracted position) but not bias the guard 32, or bias the guard 32 less, in the distal direction during a portion of or the entirety of the delivery state (e.g., during at least a portion of the time when the drug is expelled from the insertion end 28 of the delivery member 16 into the patient). As a more specific example, the proximal biasing member 35 may be configured to selectively bias the guard 32 in the distal direction when the guard

32 is in the second axial or retracted position such that the proximal biasing member 35 biases the guard 32 in the distal direction when the guard 32 is initially in the second axial or retracted position, but, subsequently, while the guard 32 is still in the second axial or retracted position, does not bias the guard 32 in the distal direction or biases the guard 32 less in the distal direction as compared to when the guard 32 is initially in the second axial or retracted position.

[0102] When the proximal biasing member 35 is not configured to bias the guard 32 in the distal direction, the plunger guide 60, via, for example, an operable coupling with rotatable member 37, may bear the distally directed biasing force of the proximal biasing member 35. As an example, the rotatable member 37 may have a first rotational position allowing the proximal biasing member to bias the guard 32 in the distal direction and a second rotational position preventing the proximal biasing member 35 from the biasing the guard 32 in the distal direction. Optionally, the rotatable member 37 may have a third rotational position, different from the first and second rotational positions, allowing the proximal biasing member 35 to bias the guard 32 in the distal direction, if, for example, the guard 32 comes into contact with the rotatable member 37 after the guard 32 has been lifted off of the injection site after an injection has been completed.

[0103] Referring to Figs. 7-11, an example will now be described of how the rotatable member 37 may facilitate a reduced holding force requirement (e.g., a reduced user holding force requirement) during at least a portion of the delivery state, among other features and functions. Figs. 7-11 are chronologically ordered and illustrate a sequence of positions of the rotatable member 37 and other components of the drug delivery device 10 during various states and sub-states of operation of the drug delivery device 10. For the sake of visual clarity, the proximal biasing member 35 is omitted from Figs. 7-11, but, in reality, as shown in Fig. 2, the proximal biasing member 35 would be positioned axially between the proximal end of the rotatable member 37 and the proximal end of the plunger guide 60 and/or with the distal end of the proximal biasing member 35 in contact with a proximally facing surface of the proximal end of the rotatable member 37 and/or with the proximal end of the proximal biasing member 35 in contact with a distally facing surface of the proximal end of the plunger guide 60. Other components of the drug delivery device 10 are also omitted from Figs. 7-11 for clarity, including, for example, the housing 12, drug storage container 20, container holder 31, and removable cap 19. In Figs. 7B, 8B, 9B, 10B, and 11B, the rotatable member 37 is omitted but the position of the plunger guide engagement member 37c of the rotatable member 37 is illustrated as a dashed line rectangle.

[0104] Figs. 7A and 7B illustrate the storage state of the drug delivery device 10. Here, the guard 32 may be positioned in its first axial or extended position such that the insertion end 28 of the delivery member 16 is covered by the guard 32, and the rotatable member 37 may be positioned in a first axial position and a first rotational position with respect to the longitudinal axis A. As seen in Fig. 7A, the proximal end 32e of the guard 32, including the proximally facing end surfaces 32g and 32h of, respectively, the longitudinally extending arms 32b and 32c of the guard 32, may be spaced by an axial gap or distance

from the distal end of the rotatable member 37. The rotatable member 37 may be biased in the distal direction (along the longitudinal axis A) by the proximal biasing member 35 (shown in Fig. 2, for example) and biased in a rotational clockwise direction (about the longitudinal axis A, when viewed from above) by the plunger biasing member 50 (shown in Fig. 3B, for example) via the engagement between the releaser member engagement member 37d of the rotatable member 37 and the rotatable member engagement member 52a of the releaser member 52. However, the rotatable member 37 may be prevented or inhibited from moving in the distal direction and rotating in the clockwise direction by an engagement between the rotatable member 37 and the plunger guide 60. As an example, as shown in Fig. 7B, the plunger guide engagement member 37c of the rotatable member 37 may engage the first rotatable member engagement member 60a of the plunger guide 60 to prevent or inhibit the rotatable member 37 from rotating in the clockwise direction. As a result, the releaser member 52, which is currently rotationally locked with the rotatable member 37 due to the engagement between the releaser member engagement member 37d of the rotatable member 37 and the rotatable member engagement member 52a of the releaser member 52, is also prevented or inhibited from rotating in the clockwise direction, which, as discussed above, prevents the plunger biasing member 50 from expanding. To restrain the rotatable member 37 from moving in the distal direction, the plunger guide engagement member 37c of the rotatable member 37 may engage a second rotatable member engagement member 60f of the plunger guide 60, as shown in Fig. 7B. The second rotatable member engagement member 60f may include a protrusion which extends radially outwardly, is disposed distal to at least a portion of the first rotatable member engagement member 60a, and has at least one surface that is perpendicular or otherwise non-parallel to the longitudinal axis A. The first rotatable member engagement member 60a and the second rotatable member engagement member 60f may define a continuous protrusion as shown in Fig. 7B or, in other embodiments, may be separate protrusions with a gap therebetween.

[0105] Figs. 8A and 8B illustrate the beginning or substantially the beginning of the delivery state. Here, the guard 32 has moved in the direction of arrow 32f (corresponding to the proximal direction) from its first axial or extended position to the second axial or retracted position due to the user pressing the guard 32 against the injection site, causing the insertion end 28 of the delivery member 16 to be inserted into the injection site. In moving from its first axial or extended position to the second axial or retracted position, the guard 32 eliminates the initial axial gap between the guard 32 and rotatable member 37 and then engages and pushes the rotatable member 37 in the direction of arrow 37e (corresponding to the proximal direction) from its first axial position to a second axial position. In moving from its first axial position to its second axial position, the rotatable member 37 may compress the axial length of the proximal biasing member 35. Furthermore, this axial movement of the rotatable member 37 may cause the plunger guide engagement member 37c of the rotatable member 37 to slide against the first rotatable member engagement member 60a of the plunger guide 60 until the plunger guide engagement member 37c clears the proximal end of the

first rotatable member engagement member 60a, as seen in Fig. 8B. Here, the plunger guide engagement member 37c of the rotatable member 37 no longer engages the first rotatable member engagement member 60a of the plunger guide 60. As a result, the plunger guide 60 no longer prevents or inhibits rotation of the rotatable member 37 or the releaser member 52 about the longitudinal axis A. As described above, this allows the plunger biasing member 50 to begin expanding in the distal direction, and, through the camming action between the plunger 26 and the plunger guide 60, rotate the releaser member 52 (see arrow 52d in Fig. 9A), which, in turn, rotates the rotatable member 37 (see arrow 37j in Fig. 9A) due to the engagement between the releaser member engagement member 37d of the rotatable member 37 and the rotatable member engagement member 52a of the releaser member 52.

[0106] Figs. 9A and 9B illustrate a moment in time during the delivery state after the rotatable member 37 has been rotated in the clockwise direction by the releaser member 52 from the first rotational position to a second rotational position. The rotatable member 37 may cease rotating in the clockwise direction upon reaching the second rotational position at least in part due to the plunger guide engagement member 37c of the rotatable member 37 engaging a third rotatable member engagement member 60g of the plunger guide 60, as seen in Fig. 9B. The third rotatable member engagement member 60g of the plunger guide 60 may include a protrusion (e.g., a longitudinally extending ridge or spline) which extends radially outwardly, is disposed near a distal end of the plunger guide 60, and has at least one surface that is parallel or substantially parallel to the longitudinal axis A. The engagement between the plunger guide engagement member 37c of the rotatable member 37 and the third rotatable member engagement member 60g of the plunger guide 60 may prevent or inhibit further clockwise rotation of the rotatable member 37 (see arrow 37j in Fig. 9A) but allow relative movement in the axial direction between the plunger guide engagement member 37c and the third rotatable member engagement member 60g.

[0107] Rotation of the rotatable member 37 from the first rotational position to the second rotational position may cause the proximally facing end surfaces 32g and 32h of, respectively, the longitudinally extending arms 32b and 32c of the guard 32 to slide against, respectively, distally facing end surfaces 37f and 37g of the rotatable member 37 until the proximally facing end surfaces 32g and 32h clear their respective distally facing end surfaces 37f and 37g, as seen in Fig. 9A. Here, the rotatable member 37 may be disengaged from the guard 32, and the longitudinally extending arms 32b and 32c of the guard 32 may align with respective recesses 37h and 37i (e.g., grooves, depressions, slots, and/or channels) formed in the outer surface of the rotatable member 37. The radial depth of each of the recesses 37h and 37i may be equal to or greater than a radial thickness of each of the longitudinally extending arms 32b and 32c of the guard 32. As a result, the longitudinally extending arms 32b and 32c may be configured to slide into or otherwise be received in, respectively, the recesses 37h and 37i formed in the outer surface of the rotatable member 37 when the rotatable member 37 is in the second rotational position. The proximal biasing member 35 may continue to exert a distally directed biasing force on the rotatable member 37 when the

rotatable member 37 is in the second rotational position. Since the longitudinally extending arms 32b and 32c are aligned with the respective recesses 37h and 37i and nothing restrains distal movement of the rotatable member 37 when the rotatable member 37 is in the second rotational position, the rotatable member 37 moves in the distal direction along the longitudinal axis A under the influence of the distally directed biasing force of the proximal biasing member 35 (see arrow 37k in Fig. 10A).

[0108] Figs. 10A and 10B illustrate a moment in time during the delivery state after the rotatable member 37 has been moved linearly in the distal direction from the second axial position to a third axial position by the proximal biasing member 35. The plunger guide engagement member 37c of the rotatable member 37 may slide against the third rotatable member engagement member 60g of the plunger guide 60 when the rotatable member 37 moves from the second axial position toward the third axial position. The rotatable member 37 may cease moving in the distal direction upon reaching the third axial position at least in part due to the plunger guide engagement member 37c of the rotatable member 37 engaging a fourth rotatable member engagement member 60h of the plunger guide 60, as seen in Fig. 10B. When the rotatable member 37 moves from the second axial position toward the third axial position, the plunger guide engagement member 37c of the rotatable member 37 may engage and impact the fourth rotatable member engagement member 60h of the plunger guide 60. The impact between the plunger guide engagement member 37c of the rotatable member 37 and the fourth rotatable member engagement member 60h of the plunger guide 60 may generate an audible signal indicating a start of dose delivery (start-of-dose signal). In some embodiments, the audible signal may be accompanied by a tactile feedback or tactile signal produced as a result of the plunger guide engagement member 37c striking the fourth rotatable member engagement member 60h. The start-of-dose audible signal may be in the form of a click or slap sound, or any other suitable audible signal that is perceptible to the user. The audible signal may be generated simultaneously, or substantially simultaneously, with the plunger guide engagement member 37c of the rotatable member 37 contacting the fourth rotatable member engagement member 60h of the plunger guide 60.

[0109] While Figs. 10A and 10B illustrate the start-of-dose audible signal being generated when the plunger guide engagement member 37c of the rotatable member 37 impact the fourth rotatable member engagement member 60h of the plunger guide 60, in some embodiments, the start-of-dose signal may be generated when the rotatable member 37 impacts another component of the drug delivery device 10. By way of example, the start-of-dose signal may be generated when the proximally facing end surfaces 32g and 32h of, respectively, the longitudinally extending arms 32b and 32c of the guard 32 engage at least a portion of the rotatable member 37 after the longitudinally extending arms 32b and 32c is fully received in, respectively, the recesses 37h and 37i formed in the outer surface of the rotatable member 37. In other embodiments, the start-of-dose signal may be generated when the distally facing end surfaces 37f and 37g of the rotatable member 37 impact, for example, at least a portion of the container holder 31. In some embodiments, the start-of-dose signal may be generated when the rotatable member 37 impacts a portion

of the housing 12 or other components of the drug delivery device 10 that remain fixed during activation. In yet another embodiment, the start-of-dose signal may be generated when the proximal biasing member 35 is released and/or when the plunger biasing member 50 is released.

[0110] When the rotatable member 37 is in the second rotational position, the proximal biasing member 35 may not bias the guard 32 in the distal direction. This is because, when the rotatable member 37 is in the second rotational position, no distally facing surface of the rotatable member 37, including the distally facing end surfaces 37f and 37g, may contact a proximally facing surface of the guard 32, including the proximally facing end surfaces 32g and 32h of, respectively, the longitudinally extending arms 32b and 32c. As a result, the rotatable member 37 may not transmit the distally directed biasing force of the proximal biasing member 35 to the guard 32. Accordingly, the user may be completely or substantially completely alleviated from having to exert a manual force counteracting the distally directed biasing force of the proximal biasing member 35 when the rotatable member 37 is in the second rotational position, which includes a portion of or the entirety of the delivery state. In embodiments where the distal biasing member 51 is included, the user may nevertheless be required to exert a manual force countering the distally directed biasing force of the distal biasing member 51. However, this will require less effort, potentially substantially less effort, than having to counteract both the distally directed biasing force of the proximal biasing member 35 and the distally directed biasing force of the distal biasing member 51. Thus, the amount of force that the user must apply to hold the guard 32 in the second axial or retracted position during the delivery state may be reduced. This may reduce the chances of the user prematurely, before the end of the delivery state, lifting the guard 32 off of the skin and/or withdrawing the insertion end 28 of the delivery member 16 from the patient, potentially resulting in the delivery of a suboptimal amount of the drug, or none at all. Moreover, a reduced holding force requirement may aid the user in holding the drug delivery device 10 steady or stably during the delivery state, making it less likely that the user moves the insertion end 28 of the delivery member 16 laterally with respect to the surrounding tissue, which can cause discomfort to the patient. As seen in Fig. 10B, the fourth rotatable member engagement member 60h of the plunger guide 60 may include a protrusion which extends radially outwardly, is disposed distal to the third rotatable member engagement member 60g, and has at least one camming surface 60i (e.g., ramp) that is arranged at an angle or slope relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A. When the rotatable member 37 is in the second rotational position and third axial position, the proximal biasing member 35 may push the plunger guide engagement member 37c of the rotatable member 37 against the camming surface 60i, thereby resulting in the plunger guide 60 bearing the distally directed biasing force of the proximal biasing member 35. The slope of the camming surface 60i may translate or convert at least a portion of the axial biasing force from the proximal biasing member 35 into a force in a transverse direction with respect to the longitudinal axis A, thereby urging the plunger guide engagement member 37c and the remainder of the rotatable member 37 to rotate about the longitudinal

axis A. However, the longitudinally extending arms 32b and 32c of the guard 32, by virtue of being positioned in, respectively, the recesses 37h and 37i in the outer surface of the rotatable member 37 as seen in Fig. 10A, may abut against the circumferentially facing surfaces of the rotatable member 37 and thereby prevent the rotatable member 37 from rotating about the longitudinal axis A. As a result, as long as the longitudinally extending arms 32b and 32c of the guard 32 are positioned in, respectively, the recesses 37h and 37i in the outer surface of the rotatable member 37, the rotatable member 37 may remain rotationally locked with respect to the guard 32 and the housing 12.

[0111] Figs. 11A and 11B illustrate the post-delivery state, after the guard 32 has been lifted off of the injection site and moved (for example, by the distal biasing member 51) in the distal direction back to its first axial or extended position to cover the insertion end 28 of the delivery member 16. As a consequence of the guard 32 moving in the distal direction from its second axial or retracted position to its first axial or extended position, the longitudinally extending arms 32b and 32c of the guard 32 may move out of their respective recesses 37h and 37i in the outer surface of the rotatable member 37. As a result, the rotatable member 37 may be freed to rotate about the longitudinal axis A. Since the proximal biasing member 35 may continue to exert a distally directed biasing force on the rotatable member 37, it may push the plunger guide engagement member 37c of the rotatable member 37 against the camming surface 60i of the plunger guide 60, causing the plunger guide engagement member 37c to slide against the camming surface 60i and thereby causing the rotatable member 37 to rotate in the counter-clockwise direction (see arrow 37j in Fig. 11A) about the longitudinal axis A from the second rotational position to a third rotational position while simultaneously moving linearly (see arrow 37n in Fig. 11A) in the distal direction along the longitudinal axis A from the third axial position to a fourth axial position. When the rotatable member 37 is positioned in the third rotational position, at least a portion of the distally facing end surfaces 37f and 37g of the rotatable member 37 may align in the rotational direction with at least a portion of, respectively, the proximally facing end surfaces 32g and 32h of longitudinally extending arms 32b and 32c of guard 32. Furthermore, when the rotatable member 37 is positioned in the third rotational position, the proximal biasing member 35 may push the plunger guide engagement member 37c of the rotatable member 37 against the rotatable member engagement member 60h of the plunger guide 60, such that the plunger guide 60 bears the distally directed biasing force of the proximal biasing member 35.

[0112] Moreover, when the rotatable member 37 is positioned in the third rotational position, further rotational movement of the rotatable member 37 in the counter-clockwise direction may be prevented by a fifth rotatable member engagement member 60k of the plunger guide 60. The fifth rotatable member engagement member 60k of the plunger guide 60 may include a protrusion which extends radially outwardly, is disposed near a distal end of the plunger guide 60, and has at least one surface that is parallel or substantially parallel to the longitudinal axis A.

[0113] As seen in Fig. 11B, when the rotatable member 37 is positioned in its third rotational position and fourth axial position, the plunger guide engagement member 37c of the rotatable member 37 may be positioned distal and immediately adjacent to a sixth rotatable member engagement member 60j of the plunger guide 60. The sixth rotatable member engagement member 60j of the plunger guide 60 may include a protrusion which extends radially outwardly, is disposed near a distal end of the plunger guide 60, and has at least one surface that is perpendicular or substantially perpendicular to the longitudinal axis A. If there is an attempt to move the guard 32 in the proximal direction from the first axial or extended position toward the second axial or retracted position after the guard 32 has been lifted off the injection site after an injection, the proximally facing end surfaces 32g and 32h of the longitudinally extending arms 32b and 32c of guard 32 may abut against or otherwise engage the distally facing distally facing end surfaces 37f and 37g of the rotatable member 37, thereby urging the rotatable member 37 in the proximal direction. However, such proximal movement of the guard 32 may be prevented or inhibited, because the plunger guide engagement member 37c may abut against or otherwise engage the sixth rotatable member engagement member 60j to prevent proximal movement of the rotatable member 37 and thus also prevent proximal movement of the guard 32. Accordingly, when the rotatable member 37 is in its third rotational position and fourth axial position, the rotatable member 37 may lock the guard 32 in the first axial or extended position to cover the insertion end 28 of the delivery member 16 in the post-delivery state after the drug delivery device 10 has been lifted off of the injection site.

[0114] While not mentioned specifically above, any one of the engagement members 37c, 37d, 52a, 60a, 60f, 60g, 60h, 60j, and/or 60k may have a respective duplicate or counterpart member whose geometry is the same except for being mirrored across the longitudinal axis A, as illustrated in some of the figures.

[0115] Having described the configuration of the drug delivery device 10, a general method of using the drug delivery device 10 to perform an injection will now be described. As a preliminary step, the user may remove the drug delivery device 10 from any secondary packaging, such as a plastic bag and/or cardboard box. Also, as a preliminary step, the user may prepare the injection site, e.g., by rubbing the patient's skin with an alcohol wipe. Next, the user may pull and detach the removable cap 19 from the housing 12. As a result of this motion, the gripper 13 may pull and detach the removable sterile barrier 21 from the drug storage container 20. This may uncover the insertion end 28 of the delivery member 16. Nevertheless, the insertion end 28 of the delivery member 16 will remain surrounded by the guard 32 at this stage because the guard 32 is arranged in the first axial or extended position. Next, the user may position the drug delivery device 10 over the injection site and then push the distal end of the guard 32 against the injection site. The force applied by the user will overcome the distally directed biasing force of the proximal biasing member 35 and (if included) the distally directed biasing force of the distal biasing member 51, thereby causing the guard 32 to retract into the opening 14 moving in the proximal direction from the first axial or extended position to the second axial or retracted position. During this proximal movement of the guard 32,

the delivery member 16 may remain stationary relative to the housing 12, and, as a result, the insertion end 28 of the delivery member 16 is caused to extend through an opening in the distal end of the guard 32, thereby piercing the patient's skin at the injection site and penetrating into the patient's subcutaneous tissue.

[0116] When the guard 32 moves from the first axial or extended position to the second axial or retracted position, the guard 32 may push the rotatable member 37 in the proximal direction from its first axial position to its second axial position. As described above, this movement of the rotatable member 37 may directly or indirectly cause several actions to occur, including, but not limited to, rotation of the rotatable member 37, rotation of the releaser member 52, release of the plunger biasing member 50, drug being moved out of the drug storage container 20 into the patient via insertion end 28 of the delivery member 16, and/or generation of an end-of-delivery signal.

[0117] After drug delivery is complete, the user may then lift the guard 32 off of the injection site. With nothing to resist it, the distal biasing member 51 may push the guard 32 in the distal direction from the second axial or retracted position to the first axial or extended position to cover the insertion end 28 of the delivery member 16. As discussed above, this distal movement of the guard 32 may cause the longitudinally extending arms 32b and 32c of the guard 32 to disengage from the rotatable member 37, thereby allowing the rotatable member 37 to move under the influence of the distally directed biasing force of the proximal biasing member 35 into a locking position which prevents subsequent retraction of the guard 32.

[0118] In the embodiments described above, the proximal biasing member 35 may not bias the guard 32 in the distal direction once the delivery state has started or shortly after the start of the delivery state, except in the event that one attempts to move the guard 32 in the proximal direction after having completed an injection and removed the guard 32 from the injection site. In alternative embodiments, the proximal biasing member may return to biasing the guard in the distal direction once the delivery state is complete to, for example, cause the guard to move in the distal direction from its second axial or retracted position to its first axial or extended position to cover the insertion end of the delivery member in the post-delivery state. Such an embodiment is described below in connection with Figs. 12-20.

[0119] Various elements of the drug delivery device 110 illustrated in Figs. 12-20 may be similar or identical in structure, configuration, function, and/or operation to elements of the drug delivery device 10 described above in connection with Figs. 1-11. Such elements are assigned with the same reference numeral as used in Figs. 1-11, except incremented by 100. A description of some of these elements is abbreviated or eliminated in the interest of conciseness. Details of the structure, configuration, and/or function that differentiate the embodiment of the drug delivery device 110 illustrated in Figs. 12-20 from the embodiment of the drug delivery device 10 illustrated in Figs. 1-11 are the focus of the discussion below.

[0120] As illustrated in Fig. 12A, the releaser member 152 may be positioned radially outwardly of the plunger guide 160. As also illustrated in Fig. 12A, at least a portion of the plunger guide 160 may be positioned radially between the releaser member 152 and the plunger 126. The releaser member 152, plunger guide 160, and plunger 126 may generally interact in a similar manner as the embodiment described above in conjunction with Figs. 1-11 to release the plunger biasing member 150 when the guard 132 moves from the first axial or extend position to the second axial or retracted position and/or to generate the end-of-delivery click, except for the latter being generated as a result of the releaser member 152 striking a distally facing surface of an outer portion of the plunger guide 160.

[0121] Fig. 13 illustrates that the rotatable member engagement member 152a of the releaser 152 may be defined by a recess (e.g., groove, depression, slot, and/or channel) formed in a radially outwardly facing surface of the releaser member 152. In alternative embodiments, the rotatable member engagement member 152a may be a radially outwardly extending protrusion. In any case, the rotatable member engagement member 152a of the releaser member 152 may be configured to engage the releaser member engagement member 137d of the rotatable member 137 such that, when the rotatable member 137 is not rotationally fixed with the plunger guide 160 due to the plunger guide engagement member 137c of the rotatable member 137 disengaging from the rotatable member engagement member 160a of the plunger guide 160, rotation of the releaser member 152 (e.g., caused by expansion of the plunger biasing member 150) causes the rotatable member 137 to rotate together with the releaser member 152 about the longitudinal axis A, for example, from a first rotational position to a second rotational position. Further features and functions of the rotatable member 137 are discussed below.

[0122] Figs. 14A and 14B show that the releaser member engagement member 137d may include a protrusion which extends radially inwardly and is disposed near the proximal end of the rotatable member 137, and that the plunger guide engagement member 137c may include a protrusion which extends radially inwardly and is disposed near a distal end of the rotatable member 137. The plunger guide engagement member 137c may include: an abutment surface 137ci which is parallel or substantially parallel to the longitudinal axis A and faces generally in a first circumferential direction; and a camming surface 137cii (e.g., a ramp) which is arranged at an angle or slope relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A. As seen in Fig. 14B, a distal end of the camming surface 137cii may be closer in the circumferential direction to the abutment surface 137ci than the proximal end of the camming surface 137cii. In alternative embodiments, the plunger guide engagement member 137c may be replaced with two separate plunger guide engagement members having, respectively, the abutment surface 137ci and the camming surface 137cii.

[0123] Figs. 12A, 12B, and 15 show that the drug delivery device 110 may include transmitter 170. The transmitter 170 may have a hollow and generally cylindrical or tubular shape, or a ring-like shape, and may be centered about the longitudinal axis A. The transmitter 170 may be axially positioned between the

rotatable member 137 and the guard 132. The transmitter 170 may be configured to move linearly along the longitudinal axis A but prevented from rotating about the longitudinal axis A. Therefore, the transmitter 170 may be configured to move linearly with respect to the housing 112 and/or plunger guide 160 but substantially or completely prevented from rotating with respect to the housing 112 and/or plunger guide 160. To achieve this effect, in some embodiments the transmitter 170 may cooperate with the plunger guide 160 to prevent relative rotational movement, but permit relative axial movement, between the transmitter 170 and plunger guide 160. For example, as illustrated in Figs. 12B and 15, an outer portion of the plunger guide 160 may include a transmitter engagement member 160m and an inner portion of the transmitter 170 may include a plunger guide engagement member 170a. The transmitter engagement member 160m may include a protrusion (e.g., a longitudinally extending ridge or spline) which extends radially outwardly, is disposed near a distal end of the plunger guide 160, and has at least one surface that is parallel or substantially parallel to the longitudinal axis A. The plunger guide engagement member 170a may be defined by a recess (e.g., groove, depression, slot, and/or channel) formed in a radially inwardly facing surface of the transmitter 170. The transmitter engagement member 160m may be configured to engage the plunger guide engagement member 170a to prevent the transmitter 170 from rotating with respect to the plunger guide 160 and housing 112, while allowing the transmitter 170 to move linearly with respect to the plunger guide 160 and housing 112. As an example, the plunger guide engagement member 170a may slide against the transmitter engagement member 160m when the transmitter 170 moves linearly with respect to the plunger guide 160 as a result of the user pushing the guard 132 in the proximal direction to activate the drive mechanism 130 and/or uncover the insertion end 128 of the delivery member 116. Additionally or alternatively, the transmitter 170 may include an anti-rotation feature that mates with a corresponding feature disposed on the inner surface of the housing 112.

[0124] Referring to Figs. 16-20, an example will now be described of how the rotatable member 137 and transmitter 170 may interact to eliminate or reduce an amount of distally directed force applied by the proximal biasing member 135 to the guard 132 during a portion of or the entirety of the delivery state and restore, in part or in whole, the amount of the distally directed force applied by the proximal biasing member 135 to the guard 132 after the delivery state, among other features and functions.

[0125] Figs. 16-20 are chronologically ordered and illustrate a sequence of positions of the rotatable member 137, transmitter 170, and other components of the drug delivery device 110 during various states or sub-states of operation of the drug delivery device 110. For the sake of visual clarity, the proximal biasing member 135 is omitted from Figs. 16-20, but, in reality, as shown in Fig. 12A, the proximal biasing member 135 would be positioned axially between the proximal end of the rotatable member 137 and the proximal end of the releaser member 152 and/or with the distal end of the proximal biasing member 135 in contact with a proximally facing surface of the proximal end of the rotatable member 137 and/or with the proximal end of the proximal biasing member 135 in contact with a distally facing surface of the proximal

end of the releaser member 152. Other components of the drug delivery device 110 are also omitted from Figs. 16-20 for clarity, including, for example, the housing 112, drug storage container 120, and removable cap 119. In Figs. 16B, 17B, 18B, and 20B, the rotatable member 137 is omitted but the position of the plunger guide engagement member 137c of the rotatable member 137 is illustrated in dashed lines.

[0126] Figs. 16A and 16B illustrate the storage state of the drug delivery device 110. Here, the guard 132 may be positioned in its first axial or extended position such that the insertion end 128 of the delivery member 116 is covered by the guard 132, the rotatable member 137 may be positioned in a first axial position and a first rotational position with respect to the longitudinal axis A, and the transmitter 170 may be positioned in a first axial position. As seen in Fig. 16A, a distally facing surface of the transmitter 170 may engage a proximally facing surface of the container holder 131 to prevent the transmitter 170 from moving in the distal direction in the storage state. Furthermore, a distally facing surface of the rotatable member 137 may engage a proximally facing surface of the transmitter 170, thereby preventing the rotatable member 137 from moving in the distal direction (e.g., under the influence of the distally directed biasing force of the proximal biasing member 135) in the storage state.

[0127] Fig. 16A further shows that the proximal end 132e of the guard 132, including the proximally facing end surfaces 132g and 132h of, respectively, the longitudinally extending arms 132b and 132c of the guard 132, may be spaced by an axial gap or distance from the distal end of the transmitter 170. The rotatable member 137 and the transmitter 170 may be biased in the distal direction (along the longitudinal axis A) by the proximal biasing member 135. The rotatable member 137 may also be biased in a rotational clockwise direction (about the longitudinal axis A, when viewed from above) by the plunger biasing member 150 via the engagement between the releaser member engagement member 137d of the rotatable member 137 and the rotatable member engagement member 152a of the releaser member 152. However, the rotatable member 137 may be prevented or inhibited from rotating in the clockwise direction by an engagement between the rotatable member 137 and the plunger guide 160. As an example, as shown in Fig. 16B, the plunger guide engagement member 137c of the rotatable member 137, particularly the abutment surface 137ci of the plunger guide engagement member 137c (shown in Figs. 14A and 14B), may engage the rotatable member engagement member 160a of the plunger guide 160 to prevent or inhibit the rotatable member 137 from rotating in the clockwise direction. As a result, the releaser member 152, which is currently rotationally locked with the rotatable member 137 due to the engagement between the releaser member engagement member 137d of the rotatable member 137 and the rotatable member engagement member 152a of the releaser member 152, is also prevented or inhibited from rotating in the clockwise direction, which, as discussed above, prevents the plunger biasing member 150 from expanding.

[0128] Figs. 17A and 17B illustrate the beginning or substantially the beginning of the delivery state. Here, the guard 132 has moved in the direction of arrow 132f (corresponding to the proximal direction) from its first axial or extended position to the second axial or retracted position due to the user pressing the

guard 132 against the injection site, causing the insertion end 128 of the delivery member 116 to be inserted into the injection site. In moving from its first axial or extended position to the second axial or retracted position, the guard 132 eliminates the initial axial gap between the guard 132 and the transmitter 170 and then engages and pushes the transmitter 170 in the direction of arrow 170b (corresponding to the proximal direction) from its first axial position to a second axial position. This axial movement of the transmitter 170 causes the rotatable member 137 to move in the direction of arrow 137e (corresponding to the proximal direction) from its first axial position to a second axial position. In moving from its first axial position to its second axial position, the rotatable member 137 may compress the axial length of the proximal biasing member 135. Furthermore, this axial movement of the rotatable member 137 may cause the plunger guide engagement member 137c of the rotatable member 137, particularly the abutment surface 137ci of the plunger guide engagement member 137c, to slide against the rotatable member engagement member 160a of the plunger guide 160 until the abutment surface 137ci clears the proximal end of the rotatable member engagement member 160a, as seen in Fig. 17B. Here, the abutment surface 137ci of the plunger guide engagement member 137c of the rotatable member 137 no longer engages the rotatable member engagement member 160a of the plunger guide 160. As a result, the plunger guide 160 no longer prevents or inhibits rotation of the rotatable member 137 or the releaser member 152 about the longitudinal axis A. As described above, this allows the plunger biasing member 150 and the proximal biasing member 135 to begin expanding in the distal direction, and, through the camming action between the plunger 126 and the plunger guide 160, rotate the releaser member 152 in the clockwise direction (see arrow 152d in Fig. 18A), which, in turn, rotates the rotatable member 137 in the clockwise direction (see arrow 137j in Fig. 18A) due to the engagement between the releaser member engagement member 137d of the rotatable member 137 and the rotatable member engagement member 152a of the releaser member 152. The rotational movement of the rotatable member 137, which at least in part is powered by the proximal biasing member 135, is configured to generate an audible signal indicating a start of dose delivery (start-of-dose signal). In some embodiments, the audible signal may be accompanied by a tactile feedback or tactile signal produced as a result of the rotational movement of the rotatable member 137. The start-of-dose signal may be generated simultaneously, or substantially simultaneously, with the rotational movement of the rotatable member 137. Additionally, or alternatively, the release of the plunger biasing member 150 may generate the start-of-dose signal. Accordingly, when the plunger biasing member 150 begins to expand in the distal direction, the plunger biasing member 150 may simultaneously, or substantially simultaneously, generate the start-of-dose signal. The start-of-dose signal may be accompanied by a tactile feedback or tactile signal produced as a result of the release of the plunger biasing member 150. In other embodiments, the camming action between the plunger 126 and the plunger guide 160 may generate the start-of-dose signal.

[0129] Figs. 18A and 18B illustrate a moment in time during the delivery state after the rotatable member 137 has been rotated in the clockwise direction by the releaser member 152 from the first rotational position to a second rotational position. As a result of moving from the first rotational position to the second rotational position, the rotatable member 137 may disengage from the transmitter 170 and the camming surface 137cii of the plunger guide engagement member 137c of the rotatable member 137 (shown in Fig. 14A) may come into contact or engagement with a rotatable member engagement 160n of the plunger guide 160. The rotatable member engagement 160n may include a protrusion which extends radially outwardly, is disposed proximal to the rotatable member engagement member 160a, and has at least one surface that is perpendicular or otherwise non-parallel to the longitudinal axis A. The rotatable member engagement members 160a and 160n may define a continuous protrusion as shown in Fig. 18B or, in other embodiments, may be separate protrusions with a gap therebetween.

[0130] When the rotatable member 137 is in the second rotational position, the proximal biasing member 135 may not bias the guard 132 in the distal direction. This is because, when the rotatable member 137 is in the second rotational position, no distally facing surface of the rotatable member 137 may contact a proximally facing surface of the transmitter 170. As a result, the transmitter 170 may not transmit the distally directed biasing force of the proximal biasing member 135 to the guard 132. Instead, due to the contact between the camming surface 137cii of the plunger guide engagement member 137c of the rotatable member 137 and the rotatable member engagement 160n of the plunger guide 160, the plunger guide 160 may bear the distally directed biasing force of the proximal member 135, when the rotatable member 137 is in the second rotational position shown in Fig. 18B. Accordingly, the user may be completely or substantially completely alleviated from having to exert a manual force counteracting the distally directed biasing force of the proximal biasing member 135 when the rotatable member 137 is in the second rotational position, which includes a portion or the entirety of the delivery state. In embodiments where the distal biasing member 151 is included, the user nevertheless may be required to exert a manual force countering the distally directed biasing force of the distal biasing member 151. However, this will require less effort, potentially substantially less effort, than having to counteract both the distally directed biasing force of the proximal biasing member 135 and the distally directed biasing force of the distal biasing member 151. Thus, the amount of force that the user must apply to hold the guard 132 in the second axial or retracted position during the delivery state may be reduced.

[0131] The rotatable member 137 may be positioned in the second rotational position only momentarily, as the rotatable member 137 may continue to rotate in the clockwise direction as a result of the proximal biasing member 135 causing a camming interaction between the camming surface 137cii of the plunger guide engagement member 137c of the rotatable member 137 and the rotatable member engagement 160n of the plunger guide 160. As an example, the slope of the camming surface 137cii may translate or convert at least a portion of the axial biasing force from the proximal biasing member 135 into a force in a

transverse direction with respect to the longitudinal axis A, thereby urging the camming surface 137cii of the plunger guide engagement member 137c and the remainder of the rotatable member 137 to rotate in the clockwise direction about the longitudinal axis A (see arrow 137k in Fig. 19). Additionally, while the rotatable member 137 is rotating, the proximal biasing member 135 may push the rotatable member 137 to move linearly in the distal direction (see arrow 137m in Fig. 19). As a result, the rotatable member 137 may rotate in the clockwise direction to a third rotational position (depicted in Fig. 19) and move distally to a third axial position (depicted in Fig. 19). Here, the plunger guide engagement member 137c of the rotatable member 137 (illustrated as being semi-transparent in Fig. 19) may come into contact with or engage a rotatable member engagement member 170c of the transmitter 170, as depicted in Fig. 19. At this state of operation, which may be during the delivery state, the plunger guide engagement member 137c of the rotatable member 137 may still be engaged with the rotatable member engagement 160n of the plunger guide 160. As a result, at this state of operation, both the plunger guide 160 and transmitter 170 may bear the distally directed biasing force of the proximal biasing member 135. In at least some embodiments, the plunger guide 160 may bear a larger share of the distally directed biasing force of the proximal biasing member 135 than the transmitter 170. For example, the plunger guide 160 may bear a majority (i.e., greater than 50%) of the distally directed biasing force of the proximal biasing member 135. Since the longitudinally extending arms 132b and 132c of the guard 132 may be in contact with the transmitter 170 (as seen in Fig. 10), the transmitter 170 may transmit at least a portion of its share of the distally directed biasing force of the proximal biasing member 135 to the guard 132. Furthermore, since the camming surface 137cii may remain in contact with the rotatable member engagement 160n of the plunger guide 160, the resulting camming interaction may continue to urge the rotatable member 137 to rotate in the clockwise direction when the rotatable member is in the third rotational position. However, due to its engagement with the rotatable member 137 and it being rotationally fixed to the plunger guide 160, the transmitter 170 may prevent further rotation of the rotatable member 137 in the clockwise direction when the rotatable member 137 has reached its third rotational position.

[0132] Figs. 20A and 20B illustrate the post-delivery state, after the guard 132 has been lifted off of the injected site and moved by the proximal biasing member 135 and/or distal biasing member 151 in the distal direction back to its first axial or extended position to cover the insertion end 128 of the delivery member 116. As a result of the guard 132 moving in the distal direction from its second axial or retracted position to its first axial or extended position, the transmitter 170 may also move in the distal direction (arrow 170d in Fig. 20A) under the influence of the distally directed biasing force of the proximal biasing member 135. This may create clearance for the plunger guide engagement member 137c to slide off of or otherwise disengage from the rotatable member engagement 160n of the plunger guide 160 and as a result come to be supported solely by the rotatable member engagement member 170c of the transmitter 170. The rotatable member engagement member 170c may include a camming surface 170ci (e.g., a ramp) which is

arranged at an angle or slope relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A. The slope of the camming surface 170ci may translate or convert at least a portion of the axial biasing force from the proximal biasing member 135 (pushing the rotatable member 137 in the distal direction) into a force in a transverse direction with respect to the longitudinal axis A, thereby urging the rotatable member 137 to rotate in the counter-clockwise direction (see arrow 137m in Fig. 20A) about the longitudinal axis A to a fourth rotational position. Additionally, while the rotatable member 137 is rotating in the counter-clockwise direction, the proximal biasing member 135 may push the rotatable member 137 to move linearly in the distal direction (see arrow 137n in Fig. 20A) to a fourth axial position.

[0133] As depicted in Figs. 20A and 20B, when the rotatable member 137 is positioned in the fourth rotational position and the fourth axial position, at least a portion of the plunger guide engagement member 137c of the rotatable member 137 may be positioned distal and immediately adjacent to a rotatable member engagement member 160j of the plunger guide 160. The rotatable member engagement member 160j of the plunger guide 160 may include a protrusion which extends radially outwardly, is disposed distal to the rotatable member engagement member 160a, and has at least one surface that is perpendicular or substantially perpendicular to the longitudinal axis A. The rotatable member engagement members 160a and 160j may define a continuous protrusion as shown in Fig. 20B or, in other embodiments, may be separate protrusions with a gap therebetween.

[0134] If there is an attempt to move the guard 132 in the proximal direction from the first axial or extended position toward the second axial or retracted position after the guard 132 has been lifted off the injection site after an injection, the proximally facing end surfaces 132g and 132h of the longitudinally extending arms 132b and 132c of the guard 132 may abut against or otherwise engage the distally facing distally facing end surface of the transmitter 170, thereby urging the transmitter 170 and rotatable member 137 in the proximal direction. However, such proximal movement of the guard 132 may be prevented or inhibited, because a proximally facing end surface of the plunger guide engagement member 137c may abut against or otherwise engage the distally facing surface of the rotatable member engagement member 160j of the plunger guide 160 to prevent proximal movement of the rotatable member 137 and thus also proximal movement of the transmitter 170 and guard 132. Accordingly, when the rotatable member 137 is in its fourth rotational position and fourth axial position, the rotatable member 137 may lock the guard 132 in the first axial or extended position to cover the insertion end 128 of the delivery member 116 in the post-delivery state after the guard 232 has been lifted off of the injection site.

[0135] While not mentioned specifically above, any one of the engagement members 137c, 137d, 152a, 160a, 160m, 160n, and/or 160j may have a respective duplicate or counterpart member whose geometry is the same except for being mirrored across the longitudinal axis A, as illustrated in some of the figures.

[0136] In the embodiments described above, rotation of the rotatable member may be achieved, in various states, via engagement between the rotatable member and the plunger guide and/or between the

rotatable member and the transmitter. In alternative embodiments, rotation of the rotatable member may be achieved, in various states, via engagement between the rotatable member and the housing. Such an embodiment is described below in connection with Figs. 21-28.

[0137] Various elements of the drug delivery device 210 illustrated in Figs. 21-28 may be similar or identical in structure, configuration, function, and/or operation to elements of the drug delivery device 110 described above in connection with Figs. 12-20. Such elements are assigned with the same reference numeral as used in Figs. 12-20, except incremented by 100. A description of some of these elements is abbreviated or eliminated in the interest of conciseness. Details of the structure, configuration, and/or function that differentiate the embodiment of the drug delivery device 210 illustrated in Figs. 21-28 from the embodiment of the drug delivery device 110 illustrated in Figs. 12-20 are the focus of the discussion below.

[0138] Fig. 21B illustrates that the rotatable member engagement member 252a of the releaser 252 may be defined by a recess (e.g., groove, depression, slot, and/or channel) formed in a radially outwardly facing surface of the releaser member 252. In alternative embodiments, the rotatable member engagement member 252a may be a radially outwardly extending protrusion. In any case, the rotatable member engagement member 252a of the releaser member 252 may be configured to engage the releaser member engagement member 237d of the rotatable member 237 such that, when the rotatable member 237 is not rotationally fixed with the housing 212 due to a housing engagement member 237f of the rotatable member 237 disengaging from the rotatable member engagement member 212a of the housing 212, rotation of the releaser member 252 (e.g., caused by expansion of the plunger biasing member 250) causes the rotatable member 237 to rotate (together with the releaser member 252) about the longitudinal axis A, for example, from a first rotational position to a second rotational position. Further features and functions of the rotatable member 237 are discussed below.

[0139] Figs. 22A and 22B show that the housing engagement member 237f of the rotatable member 237 may include a protrusion which extends radially outwardly and is disposed near the distal end of the rotatable member 237. The housing engagement member 237f may include: an abutment surface 237fi which is parallel or substantially parallel to the longitudinal axis A and faces generally in a first circumferential direction; a camming surface 237fii (e.g., a ramp) which is arranged at an angle or slope relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A; and an abutment surface 237fiii which is perpendicular or substantially perpendicular to the longitudinal axis A and faces generally in the distal direction. As seen in Figs. 22A and 22B, a proximal end of the camming surface 237fii may be closer in the circumferential direction to the abutment surface 237fi than the distal end of the camming surface 237fii. In alternative embodiments, the housing engagement member 237f may be replaced with three separate housing engagement members having, respectively, the abutment surface 237fi, the camming surface 237fii, and the abutment surface 237fiii.

[0140] Figs. 22A and 22B indicate that the rotatable member 237 may additionally include a housing engagement member 237m, which is proximal to the housing engagement member 237f. The housing engagement member 237m may include a protrusion which extends radially outwardly, is disposed near the proximal end of the rotatable member 237, and has a camming surface 237mi (e.g., a ramp) which is arranged at an angle or slope relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A. As seen in Figs. 22A and 22B, a distal end of the camming surface 237mi may be closer in the circumferential direction to the housing engagement member 237f than the proximal end of the camming surface 237mi.

[0141] Fig. 22B shows that the rotatable member 237 may additionally include a plunger guide engagement member 237p. The plunger guide engagement member 237p may include a protrusion which extends radially inwardly, is disposed near the distal end of the rotatable member 237, and has at least one surface that is perpendicular or substantially perpendicular to the longitudinal axis A generally faces in the proximal direction. As discussed below, in the post-delivery state, the plunger guide engagement member 237p may be configured to engage a rotatable member engagement member 260p of the plunger guide 260 to prevent the guard 332 from moving in the proximal direction after the guard 332 has been lifted off of the injection site after an injection. As seen in Fig. 21B, the rotatable member engagement member 260p of the plunger guide 260 may include a protrusion which extends radially outwardly, is disposed near the distal end of the plunger guide 260, and has at least one surface that is perpendicular or substantially perpendicular to the longitudinal axis A and generally faces in the distal direction.

[0142] Fig. 23 illustrates that the rotatable member engagement member 212a of the housing 212 may include a protrusion (e.g., a longitudinally extending ridge or spline) which extends radially inwardly, is disposed near a proximal end of the housing 212, and has at least one surface that is parallel or substantially parallel to the longitudinal axis A and faces generally in a second circumferential direction (opposite to the first circumferential direction).

[0143] Referring to Figs. 24-28, an example will now be described of how the rotatable member 237 and housing 212 may interact to eliminate or reduce an amount of distally directed force applied by the proximal biasing member 235 to the guard 232 during a portion of or the entirety of the delivery state and restore, in part or in whole, the amount of the distally directed force applied by the proximal biasing member 235 to the guard 232 after the delivery state, among other features.

[0144] Figs. 24-28 are chronologically ordered and illustrate a sequence of positions of the rotatable member 237 and other components of the drug delivery device 210 during various states or sub-states of operation of the drug delivery device 210. For the sake of visual clarity, the proximal biasing member 235 is omitted from Figs. 24-28, but, in reality, as shown in Fig. 21A, the proximal biasing member 235 would be positioned axially between the proximal end of the rotatable member 237 and the proximal end of the releaser member 252 and/or with the distal end of the proximal biasing member 235 in contact with a

proximally facing surface of the proximal end of the rotatable member 237 and and/or with the proximal end of the proximal biasing member 235 in contact with a distally facing surface of the proximal end of the releaser member 252. Other components of the drug delivery device 210 are also omitted from Figs. 24-28 for clarity, including, for example, the drug storage container 210 and removable cap 219.

[0145] Fig. 24 illustrates the storage state of the drug delivery device 210. Here, the guard 232 may be positioned in its first axial or extended position such that the insertion end 228 of the delivery member 216 is covered by the guard 232 and the rotatable member 237 may be positioned in a first axial position and a first rotational position with respect to the longitudinal axis A. As seen in Fig. 24, a distally facing surface of the rotatable member 237 may engage a proximally facing surface of the container holder 231 to prevent the rotatable member 237 from moving in the distal direction (e.g., under the influence of the proximally directed biasing force of the proximal biasing member 235) in the storage state.

[0146] Fig. 24 further shows that the proximal end 232e of the guard 232, including proximally facing end surfaces 232g and 232h of, respectively, the longitudinally extending arms 232b and 232c of the guard 232, may be spaced by an axial gap or distance from the distal end of the rotatable member 237. The rotatable member 237 may be biased in the distal direction (along the longitudinal axis A) by the proximal biasing member 235.

[0147] The rotatable member 237 may also be biased in a clockwise rotational direction (about the longitudinal axis A, when viewed from above) by the plunger biasing member 250 via the engagement between the releaser member engagement member 237d of the rotatable member 237 and the rotatable member engagement member 252a of the releaser member 252. However, the rotatable member 237 may be prevented or inhibited from rotating in the clockwise direction by an engagement between the rotatable member 237 and the housing 12. As an example, as shown in Fig. 24, the housing engagement member 237f of the rotatable member 237, particularly the abutment surface 237fi of the housing engagement member 237f, may engage the rotatable member engagement member 212a of the housing 212 to prevent or inhibit the rotatable member 237 from rotating in the clockwise direction. As a result, the releaser member 252, which is currently rotationally locked with the rotatable member 237 due to the engagement between the releaser member engagement member 237d of the rotatable member 237 and the rotatable member engagement member 252a of the releaser member 252, is also prevented or inhibited from rotating in the clockwise direction, which, as discussed above, prevents the plunger biasing member 250 from expanding.

[0148] Fig. 25 illustrates the beginning or substantially the beginning of the delivery state. Here, the guard 232 has moved in the direction of arrow 232f (corresponding to the proximal direction) from its first axial or extended position to the second axial or retracted position due to the user pressing the guard 232 against the injection site, causing the insertion end 228 of the delivery member 216 to be inserted into the injection site. In moving from its first axial or extended position to the second axial or retracted position, the

guard 232 eliminates the initial axial gap between the guard 232 and the rotatable member 237 and then engages and pushes the rotatable member 237 in the direction of arrow 237e (corresponding to the proximal direction) from its first axial position to a second axial position. In moving from its first axial position to its second axial position, the rotatable member 237 may compress the axial length of the proximal biasing member 235. Furthermore, this axial movement of the rotatable member 237 may cause the housing engagement member 237f of the rotatable member 237, particularly the abutment surface 237fi of the housing engagement member 237f, to slide against the rotatable member engagement member 212a of the housing 212 until the abutment surface 237fi clears the proximal end of the rotatable member engagement member 212a of the housing 212. Here, the abutment surface 237fi of the housing engagement member 237f of the rotatable member 237 no longer engages the rotatable member engagement member 212a of the housing 212. As a result, the housing 212 no longer prevents or inhibits rotation of the rotatable member 237 or the releaser member 252 about the longitudinal axis A. As described above, this allows the plunger biasing member 250 to begin expanding in the distal direction, and, through the camming action between the plunger 226 and the plunger guide 260, rotate the releaser member 252 (see arrow 252d in Fig. 26), which, in turn, rotates the rotatable member 237 (see arrow 237n in Fig. 26) due to the engagement between the releaser member engagement member 237d of the rotatable member 237 and the rotatable member engagement member 252a of the releaser member 252.

[0149] In some embodiments, the release of the plunger biasing member 250 may generate an audible signal indicating a start of dose delivery (start-of-dose signal). In some embodiments, the audible signal may be accompanied by a tactile feedback or tactile signal produced as a result of the release of the plunger biasing member 250. When the plunger biasing member 250 begins to expand in the distal direction, the plunger biasing member 250 may simultaneously, or substantially simultaneously, generate the start-of-dose signal. In other embodiments, the camming action between the plunger 226 and the plunger guide 260 may generate the start-of-dose signal.

[0150] Fig. 26 illustrates a moment in time during the delivery state after the rotatable member 237 has been rotated in the clockwise direction by the releaser member 252 from the first rotational position to a second rotational position. Rotation of the rotatable member 237 from the first rotational position to the second rotational position may cause the rotatable member 237 to move linearly in the proximal direction to a third axial position, thereby creating an axial gap between the distal end of the rotatable member 237 and the proximally facing end surfaces 232g and 232h of, respectively, the longitudinally extending arms 232b and 232c of the guard 232, as seen in Fig. 26. As a result, the proximal biasing member 235 may not bias the guard 232 in the distal direction, because the axial gap may prevent the rotatable member 237 from transmitting the distally directed biasing force of the proximal biasing member 235 to the guard 232. In some embodiments, this axial gap may persist over the duration of the delivery state, until, for example, the end-of-delivery signal or end-of-dose signal is generated.

[0151] The rotatable member 237 may move in the proximal direction when rotating from the first rotational position to a second rotational position as a result of a camming interaction between the camming surface 237fii of the housing engagement member 237f and the rotatable member engagement member 212a of the housing 212. As an example, when the camming surface 237fii is sliding against the rotatable member engagement member 212a, the slope of the camming surface 237fii may translate or convert at least a portion of the rotational force from the releaser member 252 into a linear force in the proximal direction, thereby urging the camming surface 237fii of the housing engagement member 237f and the remainder of the rotatable member 237 to move linearly in the proximal direction along the longitudinal axis A (see arrow 237g in Fig. 26). As a result, the rotatable member 237 may move proximally to its third axial position while rotating in the clockwise direction from its first rotational position to its second rotational position.

[0152] As illustrated in Fig. 26, when the rotatable member 237 is in its third axial position and second rotational position, the abutment surface 237fiii of the housing engagement member 237f of the rotatable member 237 may engage the rotatable member engagement member 212a of the housing 212. This engagement may prevent the distally directed biasing force of the proximal biasing member 235 from moving the rotatable member 237 in the distal direction with respect to the housing 212. As a result, the housing 212 (instead of the guard 232) may bear the distally directed biasing force of the proximal biasing member 235 when the rotatable member 237 is in its third axial position and second rotational position.

[0153] Fig. 27 illustrates the configuration of the drug delivery device 210 at a time when the end-of-delivery signal is generated. Here, the releaser member 252 has been rotated in the clockwise direction (see arrow 252e) into a final or end-of-delivery position as a result of a camming interaction between the releaser member 252 and the plunger guide 260 powered by the proximal biasing member 235 expanding in the proximal direction. Due to the engagement between the rotatable member engagement member 252a of the releaser member 252 and the releaser member engagement member 237d of the rotatable member 237, the rotatable member 237 may rotate (see arrow 237h) jointly together with the releaser member 252 into a third rotational position. As a result of the rotatable member 237 rotating into the third rotational position, the abutment surface 237fiii of the housing engagement member 237f of the rotatable member 237 may disengage from the rotatable member engagement member 212a of the housing 212. As a result of this disengagement, the rotatable member 237 may be free to move linearly in the distal direction under the influence of the distally directed biasing force of the proximal biasing member 235. The proximal biasing member 235 may therefore push the rotatable member 237 in the distal direction (see arrow 237i) back into engagement with the proximally facing end surfaces 232g and 232h of, respectively, the longitudinally extending arms 232b and 232c of the guard 232 (thereby eliminating the axial gap shown in Fig. 26). As a result, the proximally biasing member 235 may return to biasing the guard 232, via the rotatable member 237, in the distal direction in the post-delivery state. Accordingly, the proximally biasing

member 235 may assist in, or be solely responsible for, pushing the guard 232 in the distal direction from the second axial or retracted position to the first axial or extended position to cover the insertion end 228 of the delivery member 216 as the user lifts the guard 232 off of the injection site after the injection.

[0154] Fig. 28 illustrates the post-delivery state, after the guard 232 has been lifted off of the injected site and moved by the proximal biasing member 235 and/or distal biasing member 251 in the distal direction back to its first axial or extended position to cover the insertion end 228 of the delivery member 216. As a result of the guard 232 moving in the distal direction from its second axial or retracted position to its first axial or extended position, the rotatable member 237 may also move in the distal direction (arrow 237j in Fig. 28) under the influence of the distally directed biasing force of the proximal biasing member 235. As a result of this distal movement of the rotatable member 237, the housing engagement member 237m of the rotatable member 237, particularly the camming surface 237mi of the housing engagement member 237m, may engage the rotatable member engagement member 212a of the housing 212. The slope of the camming surface 237mi may translate or convert at least a portion of the axial biasing force from the proximal biasing member 235 (pushing the rotatable member 235 in the distal direction) into a force in a transverse direction with respect to the longitudinal axis A, thereby urging the rotatable member 237 to rotate in the clockwise direction (see arrow 237k in Fig. 28) about the longitudinal axis A to a fourth rotational position. Additionally, while the rotatable member 237 is rotating in the clockwise direction, the proximal biasing member 235 may push the rotatable member 237 to move linearly in the distal direction (see arrow 237j in Fig. 28) to a fourth axial position.

[0155] When the rotatable member 237 is positioned in the fourth rotational position and the fourth axial position, at least a portion of the plunger guide engagement member 237p of the rotatable member 237 may be positioned distal and immediately adjacent to the rotatable member engagement member 260p of the plunger guide 260. If there is an attempt to move the guard 232 in the proximal direction from the first axial or extended position toward the second axial or retracted position after the guard 232 has been lifted off the injection site after an injection, the proximally facing end surfaces 232g and 232h of, respectively, the longitudinally extending arms 232b and 232c of guard 232 may abut against or otherwise engage the distally facing distally facing end surface of the rotatable member 237, thereby urging the rotatable member 237 in the proximal direction. However, such proximal movement of the guard 232 may be prevented or inhibited, because the proximally facing surface of the plunger guide engagement member 237p of the rotatable member 237 may abut against or otherwise engage the distally facing surface of the rotatable member engagement member 260p of the plunger guide 260 to prevent proximal movement of the rotatable member 237 and thus also proximal movement of the guard 232. Accordingly, when the rotatable member 237 is in its fourth rotational position and fourth axial position, the rotatable member 237 may lock the guard 232 in the first axial or extended position to cover the insertion end 228 of the delivery member 216 in the post-delivery state after the guard 232 has been lifted off of the injection site.

[0156] While not mentioned specifically above, any one of the engagement members 237d, 237f, 237m, 237p, 252a, and/or 260p may have a respective duplicate or counterpart member whose geometry is the same except for being mirrored across the longitudinal axis A, as illustrated in some of the figures.

[0157] All features described herein, including in the specification, claims, abstract, and drawings, and all the steps in any method or process described herein, may be combined in any combination, except combinations where one or more of the features and/or steps are mutually exclusive.

[0158] As will be recognized, the systems 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.

[0159] 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.

[0160] 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.

[0161] 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).

[0162] 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.

[0163] 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:c-Met), 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- α 4 β 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), rilotumumab, 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 α 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- α 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 α 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 α mAb); HGS-ETR1 (mapatumumab; human anti-TRAIL Receptor-1 mAb); HuMax-CD20 (ocrelizumab, anti-CD20 human mAb); HuMax-EGFR (zalutumumab); M200 (volociximab, anti- α 5 β 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 α 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 β mAb (MDX-1307); anti-mesothelin dsFv-PE38 conjugate (CAT-5001); anti-PD1mAb (MDX-1106 (ONO-4538)); anti-PDGFR α antibody (IMC-3G3); anti-TGF β 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).

[0164] 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®) molecules 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 α 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-1,3-dioxo-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 KRASG12C small molecule inhibitor, or another product containing a KRASG12C 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.

[0165] 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.

[0166] 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 having an opening and a longitudinal axis;
 - a drug storage container including a delivery member having an insertion end configured to extend at least partially through the opening during a delivery state;
 - a plunger moveable in a distal direction along the longitudinal axis to expel a drug from the drug storage container through the delivery member during the delivery state;
 - a plunger biasing member configured to bias the plunger in the distal direction;
 - a guard positioned adjacent to the opening and having a first axial position with respect to the housing prior to the delivery state and a second axial position with respect to the housing during the delivery state; and
 - a proximal biasing member configured to selectively bias the guard in the distal direction.
2. The drug delivery device of claim 1, wherein the proximal biasing member is configured to not bias the guard in the distal direction during at least a portion of the delivery state.
3. The drug delivery device of claim 1, wherein the proximal biasing member is configured to bias the guard in the distal direction less during at least a portion of the delivery state as compared to prior to the delivery state.
4. The drug delivery device of any one of claims 1 or 2, wherein the proximal biasing member is configured to selectively bias the guard in the distal direction when guard is in the second axial position.
5. The drug delivery device of any one of claims 1 to 4, comprising a rotatable member moveable along the longitudinal axis and having a first rotational position allowing the proximal biasing member to bias the guard in the distal direction and a second rotational position preventing the proximal biasing member from biasing the guard in the distal direction.
6. The drug delivery device of claim 5, wherein the rotatable member has a third rotational position allowing the proximal biasing member to bias the guard in the distal direction.
7. The drug delivery device of any one of claims 5 or 6, wherein the rotatable member is positioned along the longitudinal axis between at least a portion of the guard and at least a portion of the proximal biasing member.

8. The drug delivery device of any one of claims 5 to 7, comprising a plunger guide rotationally fixed with respect to the housing, wherein, prior to the delivery state, the rotatable member is operably coupled with the plunger guide to prevent the rotatable member from rotating from the first rotational position toward the second rotational position.

9. The drug delivery device of claim 8, wherein, during at least a portion of the delivery state, the rotatable member is operably coupled with the plunger guide to prevent the proximal biasing member from biasing the guard in the distal direction.

10. The drug delivery device of claim 9, wherein, after the delivery state, the rotatable member is operably coupled with the guard to allow the proximal biasing member to bias the guard in the distal direction.

11. The drug delivery device of any one of claims 8 to 10, wherein an inner portion of the rotatable member comprises a plunger guide engagement member and an outer portion of the plunger guide comprises a first rotatable member engagement member, wherein, prior to the delivery state, the plunger guide engagement member of the rotatable member engages the first rotatable member engagement member of the plunger guide to prevent the rotatable member from rotating from the first rotational position toward the second rotational position.

12. The drug delivery device of claim 11, wherein the outer portion of the plunger guide comprises a second rotatable member engagement member, wherein, during at least a portion of the delivery state, the plunger guide engagement member of the rotatable member engages the second rotatable member engagement member of the plunger guide to prevent the rotatable member from moving in the distal direction and/or prevent the proximal biasing member from biasing the guard in the distal direction.

13. The drug delivery device of claim 12, wherein the engagement between the plunger guide engagement member of the rotatable member and the second rotatable member engagement member of the plunger guide is configured to generate at least one of an audible signal or a tactile signal indicating a start of dose delivery.

14. The drug delivery device of claim 12, wherein, after the delivery state, the plunger guide engagement member of the rotatable member disengages from the second rotatable member engagement

member of the plunger guide to allow the rotatable member to move in the distal direction and/or allow the proximal biasing member to bias the guard in the distal direction.

15. The drug delivery device of any one of claims 8 to 14, wherein the guard is configured such that the guard, when moving from the first axial position toward the second axial position, moves the rotatable member in the proximal direction to disengage the plunger guide engagement member of the rotatable member from the first rotatable member engagement member of the plunger guide to allow the rotatable member to rotate from the first rotational position to the second rotational position.

16. The drug delivery device of claim 15, wherein, prior to moving toward the second axial position, the guard is spaced from the rotatable member by an axial gap.

17. The drug delivery device of claim 5, wherein a rotational movement of the rotatable member is configured to generate at least one of an audible signal or a tactile signal indicating a start of dose delivery.

18. The drug delivery device of any one of claims 5 to 17, wherein a camming surface on one or both of the plunger and the plunger guide translates or converts an axial force from the plunger biasing member into a transverse force causing the plunger to rotate with respect to the plunger guide during an initial portion of the delivery state.

19. The drug delivery device of claim 18, comprising a releaser member, wherein, during the initial portion of the delivery state, the releaser member operably couples the plunger and the rotatable member such that rotation of the plunger during the initial portion of the delivery state causes the rotatable member to rotate from the first rotational position toward the second rotational position.

20. The drug delivery device of claim 19, wherein the inner portion of the rotatable member comprises a releaser member engagement member and an outer portion of the releaser member comprises a third rotatable member engagement member, wherein, during the initial portion of the delivery state, the third rotatable member engagement member of the releaser member engages the releaser member engagement member of the rotatable member to rotate the rotatable member from the first rotational position toward the second rotational position.

21. The drug delivery device of any one of claims 5 to 9, wherein the rotatable member includes a distally facing surface configured to engage a proximally facing surface of the guard when the rotatable

member is in the first rotational position and not engage the proximally facing surface of the guard when the rotatable member is in the second rotational position.

22. The drug delivery device of claim 21, wherein, when the guard is in the second axial position and the rotatable member is in the second rotational position, the proximal biasing member is configured to move the rotatable member in the distal direction to a position where at least a portion of a distal end of the rotator is positioned radially inward of at least a portion of the proximal end of the guard.

23. The drug delivery device of any one of claims 5 to 7, wherein, prior to the delivery state, the rotatable member is operably coupled with the housing to prevent the rotatable member from rotating from the first rotational position toward the second rotational position.

24. The drug delivery device of claim 23, wherein, during at least a portion of the delivery state, the rotatable member is operably coupled with the housing to prevent the proximal biasing member from biasing the guard in the distal direction.

25. The drug delivery device of claim 24, wherein, after the delivery state, the rotatable member is operably coupled with the guard to allow the proximal biasing member to bias the guard in the distal direction.

26. The drug delivery device of any one of claims 24 to 25, wherein an outer portion of the rotatable member comprises a first housing engagement member and an inner portion of the housing comprises a first rotatable member engagement member, wherein, prior to the delivery state, the first housing engagement member of the rotatable member engages the first rotatable member engagement member of the housing to prevent the rotatable member from rotating from the first from the first rotational position toward the second rotational position.

27. The drug delivery device of claim 26, wherein the outer portion of the rotatable member comprises a second housing engagement member, wherein, during at least a portion of the delivery state, the second housing engagement member of the rotatable member engages the first rotatable member engagement member of the housing to prevent the rotatable member from moving in the distal direction and/or prevent the proximal biasing member from biasing the guard in the distal direction.

28. The drug delivery device of claim 27, wherein, after the delivery state, the second housing engagement member of the rotatable member disengages from the first rotatable member engagement

member of the housing to allow the rotatable member to move in the distal direction and/or allow the proximal biasing member to bias the guard in the distal direction.

29. The drug delivery device of any one of claims 26 to 28, wherein the guard is configured such that the guard, when moving from the first axial position toward the second axial position, moves the rotatable member in the proximal direction to disengage the first housing engagement member of the rotatable member from the first rotatable member engagement member of the housing to allow the rotatable member to rotate from the first rotational position toward the second rotational position.

30. The drug delivery device of claim 29, wherein, prior to moving toward the second axial position, the guard is spaced from the rotatable member by an axial gap.

31. The drug delivery device of any one of claims 5 to 30, comprising a plunger guide rotationally fixed with respect to the housing, wherein at least a portion of the plunger is positioned within the plunger guide prior to the delivery state.

32. The drug delivery device of any one of claim 31, wherein a camming surface on one or both of the plunger and the plunger guide translates or converts an axial force from the plunger biasing member into a transverse force causing the plunger to rotate with respect to the plunger guide during an initial portion of the delivery state.

33. The drug delivery device of any one of claim 32, comprising a releaser member, wherein, during the initial portion of the delivery state, the releaser member operably couples the plunger and the rotatable member such rotation of the plunger during the initial portion of the delivery state causes the rotatable member to rotate from the first rotational position toward the second rotational position.

34. The drug delivery device of claim 33, wherein the inner portion of the rotatable member comprises a releaser member engagement member and an outer portion of the releaser member comprises a second rotatable member engagement member, wherein, during the initial portion of the delivery state, the second rotatable member engagement member of the releaser member engages the releaser member engagement member of the rotatable member to rotate the rotatable member from the first rotational position toward the second rotational position.

35. The drug delivery device of claim 34, wherein, after the delivery state, the second rotatable member engagement member of the releaser member engages the releaser member engagement member

of the rotatable member to rotate the rotatable member from the second rotational position toward a third rotational position.

36. A method comprising:

providing a drug delivery device comprising a housing having an opening and a longitudinal axis, a drug storage container having an insertion end configured to extend at least partially through the opening during a delivery state, a plunger moveable in a distal direction along the longitudinal axis to expel a drug from the drug storage container through the delivery member during the delivery state, a plunger biasing member configured to bias the plunger in the distal direction, a guard positioned adjacent to the opening and having a first axial position with respect to the housing prior to the delivery state and a second axial position with respect to the housing during the delivery state, and a proximal biasing member configured to selectively bias the guard in the distal direction;

moving the guard in a proximal direction from the first axial position toward the second axial position while the proximal biasing member biases the guard in the distal direction; and

holding the guard in the second axial position while the proximal biasing member at least temporarily ceases biasing, or biases less, the guard in the distal direction.

37. The method of claim 36, wherein the proximal biasing member is configured to not bias the guard in the distal direction during at least a portion of the delivery state.

38. The method of claim 36, wherein the proximal biasing member is configured to bias the guard in the distal direction less during at least a portion of the delivery state as compared to prior to the delivery state.

39. The method of any one of claims 36 or 37, wherein the proximal biasing member is configured to selectively bias the guard in the distal direction when guard is in the second axial position.

40. The method of any one of claims 36 to 39, wherein the drug delivery device comprises a rotatable member moveable along the longitudinal axis and having a first rotational position allowing the proximal biasing member to bias the guard in the distal direction and a second rotational position preventing the proximal biasing member from biasing the guard in the distal direction.

41. The method of any one of claim 40, comprising a plunger guide rotationally fixed with respect to the housing, wherein, prior to the delivery state, the rotatable member is operably coupled with the

plunger guide to prevent the rotatable member from rotating from the first rotational position toward the second rotational position.

42. The method of any one of claim 41, wherein, after the delivery state, the rotatable member is operably coupled with the guard to allow the proximal biasing member to bias the guard in the distal direction.

43. The method of any one of 36 to 41, wherein the rotatable member has distally facing surface configured to engage a proximally facing surface of the guard when the rotatable member is in the first rotational position and not engage the proximally facing surface of the guard when the rotatable member is in the second rotational position.

44. The method of any one of claims 36 to 40, wherein, prior to the delivery state, the rotatable member is operably coupled with the housing to prevent the rotatable member from rotating from the first rotational position toward the second rotational position.