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DRUG DELIVERY DEVICE

Abstract

A drug delivery device may include a housing defining a longitudinal axis and having an opening and 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. The device may also include plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, the plunger including a body portion having an inner wall defining an axial chamber and an outer wall cooperating with the inner wall to define a body thickness. The device may further include a plunger biasing member disposed at least partially within the axial chamber, the plunger biasing member configured to urge the plunger toward the distal end of the drug storage container.

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Background/Summary

CROSS-REFERENCES TO RELATED APPLICATIONS [0001] The present application is a continuation of U.S. Non-Provisional patent application Ser. No. 18/534,155, filed Dec. 8, 2023, which is a continuation of U.S. Non-Provisional patent application Ser. No. 17/036,129 (now U.S. Pat. No. 11,878,149), filed Sep. 29, 2020, which claims the priority of U.S. Provisional Application No. 62/908,504, filed Sep. 30, 2019, and U.S. Provisional Application No. 62/961,031, filed Jan. 14, 2020.

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] A general aversion to exposed needles, as well as health and safety issues, have led to the development of drug delivery devices which conceal a needle or other insertion member prior to use and which automate various aspects of an injection process. Such devices offer a variety of benefits as compared with traditional forms of drug delivery including, for example, delivery via a conventional syringe.

[0004] Many injector systems use coil and other spring structures to provide actuation energy for functions such as needle insertion and/or fluid delivery. The use of springs can offer benefits of simplicity and low cost, but it may have certain limitations. For example, there is a linear relationship between force and displacement in spring actuators. To provide sufficient energy for drug delivery at the end of plunger stroke, an excessive amount of energy may be input to the system as drug delivery commences. As another example, as higher viscosity drugs are delivered via autoinjectors, the requisite spring forces will likely increase. Springs with higher spring constants may transmit more force to the drug product and primary container. Various physical characteristics of a spring may affect the spring rate, and thus the spring force, such as wire diameter of the spring, mean diameter of the spring, the number of spring coils, and the spring material. Therefore, it may be desirable and/or advantageous to include device components that permit flexibility in spring design and/or that facilitate the use of springs with different physical characteristics with the remaining device components.

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

SUMMARY

[0006] One aspect of the present disclosure provides a drug delivery device including a housing defining a longitudinal axis and having an opening and 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. The device may further include a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, the plunger including a body portion having an inner wall defining an axial chamber and an outer wall cooperating with the inner wall to define a body thickness. The device may also include a plunger biasing member disposed at least partially within the axial chamber, the plunger biasing member configured to urge the plunger toward the distal end of the drug storage container.
[0007] The plunger body portion may have a hollow tubular shape. The plunger body portion may be made of metal or non-metal.
[0008] The plunger may be configured to selectively rotate from an initial rotational position to a second rotational position under a biasing force exerted by the plunger biasing member and to translate linearly toward the distal end of the drug storage container under the biasing force exerted by the plunger biasing member after rotating from the initial rotational position to the second rotational position.
[0009] The device may further include a plunger guide fixed relative to the housing, the plunger being disposed at least partially within the plunger guide. One of the plunger and the plunger guide may comprises a cam and the other one of the plunger and the plunger guide may comprises a cam follower.
[0010] The plunger may include the cam follower and the plunger guide includes the cam, and the cam follower may be formed by at least one flange extending radially outwardly from the plunger.
[0011] The plunger body thickness may be less than 0.6 millimeters, less than 0.4 millimeters, less than 0.3 millimeters, less than 0.2 millimeters, less than 0.1 millimeters, or less than 0.05 millimeters.
[0012] Another aspect of the present disclosure provides a drug delivery device including a housing defining a longitudinal axis and having an opening and 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. The device may further include a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, the plunger including a body portion having an inner wall defining an axial chamber and an outer wall cooperating with the inner wall to define a body thickness less than 0.6 millimeters. The device may also include a plunger biasing member coupled with the plunger and configured to urge the plunger toward the distal end of the drug storage container.

Description

BRIEF DESCRIPTION OF THE DRAWINGS
[0013] It is believed that the disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the drawings may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some drawings are not necessarily indicative of the presence or absence of particular elements in any of the exemplary embodiments, except as may be explicitly delineated in the corresponding written description. Also, none of the drawings is necessarily to scale.
[0014] FIG. **1**A is a perspective view of an exemplary drug delivery device in accordance with various embodiments;
[0015] FIG. **1**B is a perspective view of the drug delivery device in FIG. **1**A, with a cap removed therefrom;
[0016] FIG. **1**C is a perspective view of the drug delivery device in FIG. **1**A, in a pre-injection configuration;
[0017] FIG. **1**D is a perspective view of the drug delivery device in FIG. **1**A, in an injection

configuration;
[0018] FIG. **2** is cross-sectional view of the drug delivery device in FIG. **1**;
[0019] FIG. **3**A is an exploded assembly view of a portion, namely the drive mechanism, of the drug delivery device in FIG. **2**;
[0020] FIG. **3**B is an exploded assembly view of the drug delivery device in FIG. **2**;
[0021] FIG. **4**A is a perspective view of an exemplary drug storage container for use with a drug delivery device in accordance with various embodiments;
[0022] FIG. **4**B is a perspective view of an exemplary container holder for use with a drug delivery device in accordance with various embodiments, where the container holder is in an open position;
[0023] FIG. **4**C is a perspective view of the container holder in FIG. **4**B coupled with the drug storage container in FIG. **4**A, where the container holder is in a closed position;
[0024] FIG. **4**D is a perspective view of an exemplary container holder for use with a drug delivery device in accordance with various embodiments, where the container holder is in a closed position;
[0025] FIG. **4**E is a perspective view of an exemplary housing for use with a drug delivery device in accordance with various embodiments;
[0026] FIG. **4**F is a partial cross-sectional view of the container holder and the drug storage container, taken around line **4**F-**4**F in FIG. **4**C;
[0027] FIG. **5**A is a partial cross-sectional view of the container holder, the drug storage container, taken around line **5**A-**5**A in FIG. **4**C, as well as a partial cross-sectional view of a distal portion of an exemplary plunger guide coupled with the container holder and the drug storage container;
[0028] FIG. **5**B is a perspective view of an exemplary plunger guide in accordance with various embodiments;
[0029] FIG. **5**C is a perspective, partial cross-sectional view of the plunger guide in FIG. **5**B;
[0030] FIG. **6**A is a perspective view of an exemplary guard member in accordance with various embodiments;
[0031] FIG. **6**B is a perspective view of an exemplary guard extension in accordance with various embodiments;
[0032] FIG. **6**C is a perspective, partial cross-sectional, view of the guard extension, the releaser, and the plunger guide, wherein the components are in a pre-injection position;
[0033] FIG. **7**A is a perspective view of an exemplary releaser member in accordance with various embodiments;
[0034] FIG. **7**B is another perspective view of the releaser member in FIG. **7**A;
[0035] FIG. **8** is a perspective view of the plunger guide from FIG. **5**B, the releaser member from FIG. **7**A, and the plunger **26** shown in FIG. **2**, wherein the guide member is shown in translucent form for illustrative purposes;
[0036] FIG. **9**A is a perspective view of an exemplary plunger guide, an exemplary releaser member, and an exemplary plunger, wherein a portion of the guide member is shown in cut-away form for illustrative purposes, and wherein the drug delivery device is in a pre-injection position;
[0037] FIG. **9**B is a perspective view of the components from FIG. **9**A, wherein the plunger is in a released position before axial travel by the plunger;
[0038] FIG. **9**C is a perspective view of the components from FIG. **9**A, wherein the plunger is in the released position after the start of axial travel by the plunger;
[0039] FIG. **10**A is a top view of the components in FIG. **9**A, wherein the drug delivery device is in the pre-injection position;
[0040] FIG. **10**B is a top view of the components in FIG. **9**B, wherein the plunger is in the released position before axial travel by the plunger;
[0041] FIG. **10**C is a top view of the components in FIG. **9**C, wherein the plunger is in the released position after the start of axial travel by the plunger;
[0042] FIG. **11**A is a perspective view of the components in FIG. **9**A plus additional components, such as an exemplary guard extension, and wherein the drug delivery device is in a pre-injection

position;
[0043] FIG. **11**B is a perspective view of the components in FIG. **11**A, wherein the guard extension has been moved proximally but the plunger has not been released;
[0044] FIG. **11**C is a perspective view of the components in FIG. **11**A, wherein the guard extension has been further moved proximally and the plunger has released but has not yet traveled axially;
[0045] FIG. **12**A is a perspective view of the components in FIG. **9**A, plus an exemplary guard biasing member, where the plunger is in the released position after the start of axial travel by the plunger, where some of the components are shown in cut-away form for illustrative purposes;
[0046] FIG. **12**B is a perspective view of the components of FIG. **12**A, plus a more distal view of the device, where the plunger is at or near an end-of-dose release position but the releaser member is not yet at an end-of-dose position, and where the guard extension member and the guard biasing member are removed for illustrative purposes;
[0047] FIG. **12**C is a perspective view of the components of FIG. **12**A, where the releaser member is at the end-of-dose position;
[0048] FIG. **13** is a perspective view of an exemplary lock ring in accordance with various embodiments;
[0049] FIG. **14** is a perspective view of a distal portion of an exemplary device in accordance with various embodiments when a guard member is in a pre-injection, pre-deflection state, and wherein portions of the housing are shown in cut-away form for illustrative purposes;
[0050] FIG. **15**A is a perspective view of the distal portion of the device shown in FIG. **14**, where the guard member is in an initial deflection stage;
[0051] FIG. **15**B is a perspective view of the same device and the same stage as FIG. **15**A, from a view that is approximately 90 degrees from that shown in FIG. **15**A;
[0052] FIG. **16**A is a perspective view of the distal portion of the device shown in FIG. **14**, where the guard member further deflected distally from the stage shown in FIG. **15**A;
[0053] FIG. **16**B is a perspective view of the same device and the same stage as FIG. **16**A, from a view that is approximately 90 degrees from that shown in FIG. **16**A;
[0054] FIG. **17** is a perspective view of the distal portion of the device shown in FIG. **14**, where the guard member is in a fully-deflected or near fully-deflected position with respect to the housing, such as during an injection stage;
[0055] FIG. **18**A is a perspective view of the distal portion of the device shown in FIG. **14**, where the guard member is in a fully-retracted, locked-out position with respect to the housing, and the device is in a post-injection stage;
[0056] FIG. **18**B is a perspective view of the distal portion of the device shown in FIG. **14**, where the guard member is in a near fully-retracted, locked-out position with respect to the housing, and the device is in a post-injection stage;
[0057] FIG. **19**A is a graph showing an exemplary force profile during the injection process of an exemplary drug delivery device, where relative displacement between the device housing and the guard member is plotted along the x-axis (in millimeters) and resistance is plotted along the y-axis (Newtons);
[0058] FIG. **19**B is another exemplary force profile during the injection process of an exemplary drug delivery device, similar to that in FIG. **19**A;
[0059] FIGS. **20**A-**20**G show another exemplary drug delivery device in accordance with various embodiments;
[0060] FIGS. **21**A-**21**F show yet another exemplary drug delivery device in accordance with various embodiments;
[0061] FIG. **22** shows the guard member shown in FIGS. **20**A-**20**G and FIGS. **21**A-**21**F;
[0062] FIG. **23** shows the lock ring shown in FIGS. **20**A-**20**G;
[0063] FIG. **24** shows the force profiles of various devices, with two of the force profiles shown in FIGS. **19**A and **19**B, respectively, one force profile (illustrated as a dashed line) attributable to the

device **400** shown in FIGS. **20**A-**20**G, and another force profile (illustrated as a dotted line) attributable to the device **500** shown in FIGS. **21**A-**21**F;
[0064] FIG. **25** illustrates a perspective view of an exemplary housing in accordance with various embodiments; and
[0065] FIGS. **26**A-**26**D depict another exemplary drug delivery device in accordance with various embodiments, with FIGS. **26**A and **26**B illustrating different perspective views of a lock ring of the drug delivery device, FIG. **26**C illustrating a perspective view of a guard member of the drug delivery device, and FIG. **26**D illustrating a cutaway view of a portion of the drug delivery device.
DETAILED DESCRIPTION
[0066] The present disclosure generally relates to drug delivery devices operable by a user for administering a drug, or in the case where a patient is the user, self-administering a drug. Various features are disclosed for streamlining, simplifying, automating and/or facilitating certain aspects of drug delivery, such as those utilized in auto-injectors, on-body injectors, 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 inserting a needle and/or a cannula into a user, automatically activating a drive mechanism, automatically indicating to the user that drug delivery is complete, among other features. Although known drug delivery devices incorporate a separate or independently operable mechanism to realize each of its automated features, the present disclosure includes eliminating and/or combining at least some of these features and/or providing device components that permit flexibility in device design. For example, the device may include components that permit flexibility in spring design and/or that facilitate the use of springs with different physical characteristics with the remaining device components. As another example, the device may include components that reduce the part number, part complexity, overall weight of the device, and/or overall complexity of the device. For example, the present disclosure may include a plunger moveable toward the distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, where the plunger includes a body portion having an inner wall defining an axial chamber and an outer wall cooperating with the inner wall to define a body thickness. The present disclosure may also include a plunger biasing member disposed at least partially within the axial chamber, where the plunger biasing member is configured to urge the plunger toward the distal end of the drug storage container.
[0067] 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 biologicals such as peptides, peptibodies, or antibodies. The drug may be in a fluid or liquid form, although the disclosure is not limited to a particular state.
[0068] 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 exemplary the 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.
[0069] The configuration of various components included in the drug delivery device **10** may depend on the operational state of the drug delivery device **10**. The drug delivery device **10** may have a pre-delivery or storage 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 pre-delivery state may correspond to the configuration of the drug delivery device **10** subsequent to assembly and prior to activation by the user. In some embodiments, the pre-delivery

state may exist in the time between when the drug delivery device **10** leaves a manufacturing facility and when a patient or user activates a drive mechanism **30** of the drug delivery device **10**. This includes the moments in time after the user has removed the drug delivery device **10** from any secondary packaging and prior to positioning the drug delivery device **10** against the injection site. The delivery state may correspond to the configuration of the drug delivery device **10** while drug delivery, also referred to herein as dosing, is in progress. The post-delivery state may correspond to the configuration of the drug delivery device **10** after drug delivery is complete and/or when a stopper is arranged in an end-of-dose position in a drug storage container.

[0070] As shown in FIGS. **1**A and **1**B, the drug delivery device **10** includes an outer casing or housing **12**. In some embodiments, the housing **12** may be sized and dimensioned to enable a person to grasp the injector **10** in a single hand. The housing **12** may have a generally elongate 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. **3**B) may be formed in the distal end to permit an insertion end **28** of a delivery member **16** (FIG. **2**) to extend outside of the housing **12**. A transparent or semi-transparent inspection window **17** (FIGS. **1**A-**1**B) may be positioned in a wall of the housing **12** to permit a user to view component(s) inside the drug delivery device **10**, including a drug storage container **20**. Viewing the drug storage container **20** through the window **17** may allow a user to confirm that drug delivery is in progress and/or complete. A removable cap **19** may cover the opening **14** prior to use of the drug delivery device **10**, and, in some embodiments, may including a gripper **13** (FIG. **2**) configured to assist with removing a sterile barrier **21** (e.g., a rigid needle shield (RNS), a non-rigid needle shield (nRNS), etc.) mounted on the insertion end **28** of the delivery member **16**. The gripper **13** may include one or more inwardly protruding barbs or arms that frictionally or otherwise mechanically engage the sterile barrier **21** to pull the sterile barrier **21** with the removable cap **19** when the user separates the removable cap **19** from the housing **12**. Thus, removing the removable cap **19** has the effect of removing the sterile barrier **21** from the delivery member **16**.

[0071] As shown in FIG. **2**, the drive mechanism **30** may be disposed partially or entirely within the housing **12**. Generally, the drive mechanism **30** may be configured to store energy and, upon or in response to activation of the drive mechanism **30** by the user, release or output that energy to drive the plunger **26** to expel the drug **22** from the drug storage container **20** through the delivery member **16** into the patient. In the present embodiment, the drive mechanism **30** is configured to store mechanical potential energy; however, alternative embodiments of the drive mechanism **30** may be configured differently, for example, with the drive mechanism **30** storing electrical or chemical potential energy. Generally, upon activation of the drive mechanism **30**, the drive mechanism **30** may convert the potential energy into kinetic energy for moving the plunger **26**. As best illustrated in FIG. **3**A, in one embodiment, the drive mechanism **30** includes the plunger biasing member **50**, a hollow rod **46** for supporting the plunger biasing member **50**, a plunger biasing member seat **38**, the releaser member **52**, a plunger guide **60**, an extender biasing member **35**, and a guard extension **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 de-energized state. When released, the plunger biasing member **50** may try to expand to its natural axial length, and as a consequence, exert a biasing force pushing the plunger **26** in the distal direction.

[0072] As best shown in FIGS. **2** and **3**B, in one embodiment the device **10** include a 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. **3**A). 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.

[0073] The drug storage container **20** is disposed within an interior space of the housing **12** and is configured to contain a drug **22**. The drug storage container **20** may be pre-filled and shipped, e.g., by a manufacturer, to a location where the drug storage container **20** is combined with a remainder of the drug delivery device **10**. For example, the drug **22** may be distributed and/or provided to patients in more than one use case, such as a as a pre-filled syringe or as an autoinjector including a pre-filled syringe. By utilizing the same or similar syringe components in either case, at least some of above steps such as filling, labeling, packaging, shipping, and distribution may be streamlined or simplified for two different use cases. As a 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.

[0074] 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 proximal end and a distal end of the drug storage container **20**. The stopper **24** may be constructed of rubber or any other suitable material. The stopper **24** may slidably and sealingly contact an interior surface **15** of the wall of the drug storage container **20** such that the drug **22** is prevented or inhibited from leaking past the stopper **24** when the stopper **24** is in motion. Distal movement of the stopper **24** expels the drug **22** from the reservoir of the drug storage container **20** into the delivery member **16**. The proximal end of the drug storage container **20** may be open to allow a plunger **26** to extend into the drug storage container **20** and push the stopper **24** in the distal direction. In the present embodiment, the plunger **26** and the stopper **24** are initially spaced from each other by a gap **18** (FIG. **2**). Upon activation of a drive mechanism **30**, the plunger **26** moves in the distal direction to close the gap and comes into contact with the stopper **24**. Subsequent distal movement of the plunger **26** drives the stopper **24** in the distal direction to expel the drug **22** from the drug storage container **20**. In alternative embodiments, the stopper **24** and the plunger **26** may initially be in contact with one another or coupled to one another, e.g., via a threaded coupling, such that they move together jointly from the start of movement of the plunger **26**. Once the stopper **24** is in motion, it may continue to move in the distal direction until it contacts a proximally-facing portion of the interior surface **15** of the wall of the drug storage container **20**. This position of the stopper **24** may be referred to as the end-of-dose or end-of-delivery position, and may correspond to when delivery of the drug **22** to the patient is complete or substantially complete.

[0075] 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., +10%) 1 mL, or equal to 2.5 mL, or equal to approximately (e.g., +10%) 2.5 mL, or equal to 3 mL, or equal to approximately (e.g., +10%) 3 mL, or less than or equal to approximately (e.g., +10%) 1 mL, or less than or equal to approximately (e.g., +10%) 2 mL, or less than or equal to approximately (e.g., +10%) 3 mL, or

less than or equal to approximately (e.g., +10%) 4 mL, or less than approximately (e.g., +10%) 5 mL, or less than or equal to approximately (e.g., +10%) 10 mL, or within a range between approximately (e.g., +10%) 1-10 mL, or within a range between approximately (e.g., +10%) 1-5 mL, or within a range between approximately (e.g., +10%) 1-4 mL, or within a range between approximately (e.g., +10%) 1-3 mL, or within a range between approximately (e.g., +10%) 1-2.5 mL.

[0076] 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.

[0077] In one embodiment, the drug storage container **20** may be a pre-filled syringe and has a staked, hollow metal needle for the delivery member **16**. Here, the needle is fixed relative to the wall of the drug storage container **20** and may be in permanent fluid communication with the reservoir of the drug storage container **20**. In other embodiments, the needle may be coupled to the drug storage container **20** via a Luer Lock or other suitable connection. In yet other embodiments, the drug storage container **20** may be a needle-less cartridge, and, as such, initially may not be in fluid communication with the delivery member **16**. In such embodiments, the drug storage container **20** may move toward a proximal end of the delivery member **16**, or vice versa, during operation of the drug delivery device **10** such that the proximal end of the delivery member **16** penetrates through a septum covering an opening in the drug storage container **20** thereby establishing fluid communication between the reservoir of the drug storage container **20** and the delivery member **16**.

[0078] The drug storage container **20** may include a body portion **20***g* with a distal end **20***e* and a proximal end **20***f*. The drug storage container **20** may be fixed relative to the housing **12** such that the drug storage container **20** does not move relative to the housing **12** once installed in the housing **12**. As such, the insertion end **28** of the delivery member **16** extends permanently through the opening **14** in the housing **12** in the pre-delivery, delivery, and post-delivery states. For example, as shown in FIG. **2**, the delivery member **16** extends beyond a distal end of the housing **12** that defines the opening **14**. However, in some configurations, such as the storage configuration shown in FIG. **2**, the delivery member **16** is covered/protected by the sterile barrier **21** and a guard member **32** that surrounds the delivery member **16** and protects against or reduces the likelihood of unintended or premature needle stick.

[0079] 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 an inwardly protruding flange **33** abutting against a shoulder portion **20***a* of the drug storage container **20**, thereby preventing distal movement of the drug storage container **20** during actuation of the plunger **26**.

[0080] In one embodiment, a container holder **31** secures and/or fixes the position of the drug storage container **20** within the housing **12**. For example, the container holder **31** may be configured to support the drug storage container **20** with respect to the housing **12** proximal to at least a portion of the distal end of the body portion of the drug storage container **20** (including, for example, proximal to an entirety of the distal end of the body portion of the drug storage container **20**) such that a resultant force acting on the drug storage container **20** from the plunger biasing member **50** is at least substantially completely borne by the distal end of the body portion of the drug storage container **20**.

[0081] The term “body portion” of the drug storage container **20** as used herein is the generally

cylindrical portion of the drug storage container **20**. For example, the body portion **20***g* of the drug storage container **20** shown in FIG. **4**A extends from the distal side of the flange **20***c* to the proximal side of the shoulder portion **20***a*. As a more specific example, the body portion **20***g* of the drug storage container **20** shown in FIG. **4**A has a relatively constant inner diameter and/or a relatively constant outer diameter along its length. As shown in FIGS. **4**A and **2**, proximal to the distal end **20***e* of the body portion **20***g*, the drug storage container **20** defines the shoulder portion **20***a*. The delivery member **16** extends distally from the distal end **20***e* of the body portion **20***g* of the drug storage container **20**. As a more specific example, the drug storage container **20** further includes a neck portion **20***g* positioned distally of the shoulder portion **20***a* and configured to support the delivery member **16** such as a staked needle.

[0082] The term "resultant force" refers to force the urging the drug storage container **20** along the axis A upon and due to actuation of the plunger biasing member **50** during and after the injection state. For example, when the plunger **26** is actuated and driven in the distal direction along axis A, it urges the stopper **24** in the distal direction. As a result of this direct contact between the plunger **26** and the stopper **24**, as well as frictional forces between the stopper **24** and the drug storage container **20** and the forces required to urge the drug **22** through the relatively small-diameter delivery member **16**, the drug storage container is urged in a distal direction even though the plunger **26** may not directly touch, abut, or engage the body portion of the drug storage container **20**. As a result, the drug storage container **20** may experience a relatively high resultant force during the injection process, more specifically during the actuation of the plunger **26**.

[0083] The force concentration of the resultant force acting on the drug storage container **20** during the plunger actuation is highest in the portion of the drug storage container **20** that is resisting distal movement. For example, in the device shown in the figures, the force concentration is highest proximal to at least a portion of the distal end **20***e* of the body portion **20***g* of the drug storage container **20**. As a more specific example, the force concentration is highest at the shoulder portion **20***a* where the drug storage container **20** is supported by the container holder **31**. As an even more specific example, the force concentration is at least substantially completely borne by the shoulder portion **20***a* of drug storage container **20**. The term "substantially completely" may mean greater than 50%, it may mean greater than 70%, it may mean greater than 75%, it may mean greater than 80%, it may mean greater than 80%, it may mean greater than 85%, it may mean greater than 90%, it may mean greater than 95%, it may mean greater than 98%, or any other suitable number.

[0084] The force concentration of the resultant force acting on the drug storage container **20** during the plunger actuation is preferably not significantly borne by the outwardly protruding flange **20***d* of the drug storage container **20**. For example, because the force is substantially completely borne by the distal portion **20***e* of the body portion **20***g* of the drug storage container **20**, the force concentration in and near the outwardly protruding flange **20***d* is relatively low. As a more specific example, the percentage of the resultant force acting on the entire drug storage container **20** that is borne by the outwardly protruding flange **20***d* may be less than 20%, or it may be less than 15%, or it may be less than 10%, or it may be less than 5%, or it may be less than 3%, or it may be less than 2%, or it may be less than 1%, or it may be about 0%.

[0085] As shown in FIGS. **2** and **4**B, the container holder **31** includes a plurality flanges **33** that each include an arcuate, sloped surface **33***a* that substantially matches the arcuate shape of the shoulder portion **20***a* 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** cooperate to support the shoulder portion **20***a* and limit the travel of the drug storage container **20** in the distal direction. The flanges **33** are separated from each other by a gap **33***b* (FIG. **3***b*) to permit flex of the flanges **33**, as will be discussed below in more detail. The container holder **31** shown in FIGS. **4**A-**4**C includes four flanges **33**, but any suitable number of flanges may be utilized, as will be discussed below with respect to another exemplary design shown in FIG. **4**D.

[0086] The container holder **31** may have an open position **29***a* (FIG. **4**B) where it is able to receive

the drug storage container **20** during assembly and a closed position **29***b* (FIG. **4**C) where it is able to support or at least partially support the drug storage container **20**. As a more specific example, the container holder **31** includes a pair of arms **31***a*, **31***b* extending axially from an annular ring **31***c* such that the arms **31***a*, **31***b* can flex away from or towards each other to move between the open position **29***a* and the closed position **29***b*. The annular ring **31***c* in the figures is positioned near the distal end of the container holder **31** so that the proximal portions of the arms **31***a*, **31***b* are able to extend away from each other when the container holder **31** is in the open position **29***a*. The container holder **31** further includes mating connectors **31***d*, **31***e* adjacent the top (proximal) portion of the container holder **31** that are configured to snap-fit with each other when the container holder is in the closed position **29***b*. As a more specific example, when the mating connectors **31***d*, **31***e* are engaged with each other, a frictional fit between the respective components holds the container holder **31** in the closed position **29***b*.

[0087] The container holder **31** shown in the figures also includes a pair of inwardly-protruding flanges **31***f*, **31***g* positioned adjacent to the proximal end of the container holder **31**. When the container holder **31** is in the open position **29***a*, the inwardly-protruding flanges **31***f*, **31***g* are spaced apart from each other such that a radially outwardly-protruding flange **20***b* on the drug storage container **20** is able to be placed into the container holder **31** (via insertion in the distal direction). In other words, when the container holder **31** is in the open position **29***a* the outwardly-protruding flange **20***b* on the drug storage container **20** is able to clear the gap between the inwardly-protruding flanges **31***f*, **31***g*. Once the drug storage container **20** is fully inserted within the container holder **31** (e.g., such that the shoulder portion **20***a* of the drug storage container **20** contacts the inwardly-protruding flanges **33**) the container holder arms **31***a*, **31***b* are able to be moved into the closed position **29***b*, in which the inwardly-protruding flanges **31***f*, **31***g* prevent the drug storage container **20** from exiting the container holder **31** in the proximal direction. In other words, once the drug storage container **20** is inserted into the container holder **31** and the drug storage container **20** is in the closed position **29***b*, the drug storage container **20** is held within the container holder **31** by the inwardly protruding flanges **33** near the distal end of the container holder **31** and by the inwardly-protruding flanges **31***f*, **31***g* near the proximal end of the container holder **31**.

[0088] As shown in FIGS. **4**B and **4**C, the container holder **31** includes opposing surfaces **31***i*, **31***h* defining an opening **31***j* for receiving the flange **20***b* of the drug storage container **20**. For example, the container holder **31** shown in the figures includes two distally-facing surfaces **31***i* and two proximally-facing surfaces **31***h* that respectively cooperate to define two openings **31***j* that each receive opposing portions of the flange **20***b*. The opposing surfaces **31***h*, **31***i* define the lower and upper boundaries for positioning of the flange **20***b* when the drug storage container **20** is positioned within the container holder **31** in the closed position **29***b*. This range from lower and upper boundaries may provide flexibility for drug storage containers **20** of varying lengths and/or for a range of tolerances for the length of the drug storage container **20**. However, as discussed in more detail below, additional components of the device **10** may further secure the drug storage container **20** adjacent to the flange **20***b* when the drug storage container **20**/container holder **31** assembly is inside of the housing **12**. The openings **31***j* may also prevent and/or restrict rotational movement of the drug storage container **20**. For example, opposing rounded sections **20***c* of the flange **20***b* may each extend at least partially through the openings **31***j* and opposing linear sections **20***d* of the flange **20***b* may each abut side walls defining the openings **31***j* to prevent and/or restrict rotational movement between the respective components **20**, **31**.

[0089] As shown in FIG. **4**B, the container holder **31** may include additional mating connectors **31***k*, **31***m*, which are distally positioned from the mating connectors **31***d*, **31***e*. The respective pairs of mating connectors **31***d*, **31***e*; **31***k*, **31***m* may work together to create a snap fit between the respective arms **31***a*, **31***b* of the container holder **31** to secure the same in the closed position **29***b*.

[0090] It may be desirable for the annular ring **31***c* to be positioned generally opposite(along axis

A) of the mating connectors **31***d*, **31***e* to facilitate opening and closing of the container holder arms **31***a*, **31***b*. For example, the distance between the annular ring **31***c* and the inwardly-protruding flanges **31***f*, **31***g* may be proportional to the clearance gap between the inwardly-protruding flanges **31***f*, **31***g* when the container holder **31** is in the open position **29***a*. Therefore, to maximize the gap between the inwardly-protruding flanges **31***f*, **31***g* when the container holder **31** is in the open position **29***a*, one can maximize the distance between the annular ring **31***c* and the inwardly-protruding flanges **31***f*, **31***g* (e.g., the effective length of the arms **31***a*, **31***b*). Additionally, the thickness, height, and material properties of the annular ring **31***c* may each affect the flex of the arms **31***a*, **31***b* and/or the gap between the inwardly-protruding flanges **31***f*, **31***g* when the container holder **31** is in the open position **29***a*. As discussed above, the gap **33***b* between the flanges may also facilitate and/or define the amount of flex of the arms **31***a*, **31***b* and/or the gap between the inwardly-protruding flanges **31***f*, **31***g* when the container holder **31** is moved into the open position **29***a*. For example, as the arms **31***a*, **31***b* flex outwardly, the flanges **33** may move inwardly.

[0091] The container holder **31** shown in the drawings may include an alignment ridge **31***n* that abuts an inner surface of the housing **12**, to radially align the container holder **31** within the housing **12** during assembly and to prevent and/or restrict radial movement between the respective components **12**, **31**. As an example, the housing **12** may include a slot **12***a* formed on the inner surface of the housing to receive the alignment ridge **31***n*. The housing **12** may include multiple slots and the container holder **31** may include multiple alignment ridges to radially align the respective components **12**, **31**. For example, the container holder **31** shown in the figures includes two alignment ridges **31***n* and the housing **12** includes two slots **12***a*. The slots **12***a* are spaced apart from each other and sized such as to receive the respective alignment ridges **31***n* when the container holder **31** is inserted into the housing **12**. The slots **12***a* shown in the figures are defined by a generally annular collar **12***d* portion that is integral with the housing **12** (although the collar portion may alternatively be one or more components coupled or fixed to the housing). The annular collar **12***d* may not extend around the entire inner surface of the housing **12** and instead has cut-outs or gaps to permit portions of the guard member **32** to extend between respective portions of the annular collar **12***d*. Alternatively, the annular collar **12***d* may be radially inwardly spaced apart from the inner surface of the housing **12** in at least one or more locations to facilitate portions of the guard member to extend past the collar **12***d*.

[0092] The annular collar **12***d* may further define sloped surfaces **12***e* on opposite sides of each of the lock slots **12***c* to further assist with alignment between the container holder **31** and the housing **12**.

[0093] The components shown in FIGS. **4**A, **4**B, and **4**C includes an alignment ridge **31***n* that is positioned at the distal end of a support ridge **310**. For example, the support ridge **310** has a smaller height (measured perpendicularly to the outer surface of the container holder **31**) than the alignment ridge **31***n* such that only the alignment ridge **31***n* is received within the alignment slot **12***a*, rather than the support ridge **310**. Alternatively, the alignment ridge may extend substantially or completely along the axial length of the container holder **31**, as will be discussed below with respect to another exemplary design shown in FIG. **4**D.

[0094] The drug storage container **20** may be further or more securely coupled with the container holder **31** (and as a result, to the housing **12**) such that the drug storage container **20** and the container holder **31** are prevented from moving relative to the housing **12** during operation of the drug delivery device **10**. For example, as shown in FIGS. **4**B and **4**C, the container holder **31** may include a plurality of lock ridges **33***c* on the flanges **33** that form a friction-fit with portion(s) of the housing **12**. As a more specific example and as shown in FIGS. **2** & **3**B, the housing **12** includes a plurality of lock slots **12***c* that each receive respective lock ridges **33***c* of the container holder **31** to prevent and/or restrict relative movement between the respective components **12**, **31**. As a more specific example, the lock ridges **33***c* each extend radially from the outer surfaces of the flanges **33**. The container holder **31** may include any suitable number of lock ridges **33***c*, such as one, two,

three, four, or more. The lock slots **12***c* shown in the figures are defined by the annular collar **12***d*, but they may be alternatively defined by another component. The lock slots **12***c* are spaced apart from each other and sized such as to receive the respective lock ridges **33***c* when the drug storage container is positioned within the container holder **31**. As a more specific example, the lock ridges **33***c* snap into a friction-fit with the lock slots **12***c* such as to secure the container holder **31** and, as a result, the drug product container **20**, within the housing **12**. As an even more specific example, when the lock ridges **33***c* snap into the lock slots **12***c*, the flanges **33** may inwardly compress slightly to form a more-secure fit between the container holder **31** and the drug product container **20**.

[0095] The container holder **31** inner surface may include a compressible component such as an elastomeric component that is positioned between the inner surface of the container holder **31** and the drug product container **20**. As a more specific example, the elastomeric component may be a rubber ring. Alternatively or additionally, the natural flex of the flanges **33** may function as the compressible component.

[0096] The lock ridges **33***c* may give audible and/or tactile feedback to the user or an assembly worker as they snap into the corresponding lock slots **12***c*, thereby indicating to the assembler(s) that the respective components **12**, **31** are positioned as desired. Additionally, the respective components may be sized and positioned such that the feedback only occurs when the drug product container **20** is also positioned as desired. For example, if the drug product container **20** is positioned too far in the distal direction with respect to the container holder **31**, such that the main body of the drug product container **20** is aligned with the flanges **33** instead of the shoulder portion **20***a* being aligned with the flanges **33**, then the lock ridges **33***c* may not be able to radially compress enough for the lock ridges **33***c* to fit within the lock slots **12***c*. Conversely, if the drug product container **20** is not inserted far enough in the distal direction with respect to the container holder **31**, such that the sterile barrier **21** is aligned with the flanges **33** instead of the shoulder portion **20***a* being aligned with the flanges **33**, then the lock ridges **33***c* will be able to radially compress inward to an extent that the lock ridges **33***c* will be able to slide radially inward of the lock slots **12***c* or the lock ridges **33***c* will enter the lock slots **12***c* but may not cause enough radially-outward force to generate the audible and/or tactile feedback. While the audible and/or tactile feedback may be advantageous during manual assembly of the container holder **31**, assembly of the container holder **31** need not be performed manually and may in some embodiments be performed partially or entirely by manufacturing equipment.

[0097] The housing **12**, container holder **31**, and their respective components as described above offer many advantages. For example, by securely coupling the drug product container **20** with respect to the housing **12** via the shoulder portion **20***a* (as opposed to the flange portion) the device **10** may have reduced incidence of glass breakage or other damage. As a more specific example, drug product containers such as syringes are often have a shoulder portion that is stronger and/or able to handle higher forces than a flange portion. In other words, it may be advantageous for the force concentration on the drug product container to be higher at the shoulder than at the flange because the shoulder may be stronger and more resistant to breakage than the flange.

[0098] As another potential advantage to this configuration, by securely coupling the drug product container **20** with respect to the housing **12** via a distal portion (e.g., the shoulder portion **20***a*) the device **10** may have a more predictable, repeatable, and/or consistent injection depth than designs that secure the drug product container **20** via the flange (e.g. a “hanging” design). For example, the distance between the shoulder portion **20***a* and the delivery member **16** for a syringe is typically more predictable and/or has a smaller manufacturing tolerance than the distance between the flange **20***b* and the delivery member **16** because barrel length of a drug product container **20** can vary more widely than the barrel shoulder length. Additionally or alternatively, the distance between the flange **20***b* and the delivery member **16** includes any tolerances/variances in the distance between the shoulder portion **20***a* and the delivery member **16**, so any tolerances/variances are “stacked.”

[0099] As shown in FIG. **4**C, when the drug storage container **20** is inserted into the container holder **31** and the drug storage container **20** is in the closed position **29***b*, a portion of the drug storage container **20** extends past the distal end of the container holder **31**. For example, the sterile barrier **21** is positioned substantially or completely outside of the container holder **31** to facilitate removal of the sterile barrier **21** during use of the device **10**, as is shown in FIGS. **4**C and **4**F and as will be discussed in more detail below. Additionally, the delivery member **16** extends past the distal end of the container holder **31** (as discussed above).

[0100] FIG. **4**D shows another exemplary container holder **131** that has some features which are similar in function to those included in the container holder **31**, each of which is assigned with same reference numeral except incremented by 100. For example, the container holder **131** includes a pair of arms **131***a*, **131***b*; an annular ring **131***c* connecting the arms **131***a*, **131***b*; respective sets of mating connectors **131***d*, **131***e*, **131***k*, **131***m* for selectively fixing the arms in a closed position **129***b*; a pair of inwardly-protruding flanges **131***f*, **131***g*; a pair of opposing surfaces **131***h*, **131***i* for defining lower and upper limits of travel for the drug storage container flange; and an opening **131***j* for receiving the drug storage container flange. The container holder **131** also includes a plurality of flanges **133** positioned at a distal end of the container holder **131** and configured to support the drug storage container. For example, the container holder **131** includes two flanges **133**, each of which includes an arcuate, sloped surface **133***a* that substantially matches the arcuate shape of a shoulder portion of the drug storage container. The container holder **131** shown in FIG. **4**D has two flanges **133** as opposed to the four flanges **33** shown in the container holder **31** shown in FIGS. **4**A-**4**C; therefore the flanges **133** each preferably have a greater circumference than the flanges **33**. The container holder **131** also includes an alignment ridge **131***n* that is received within an alignment slot **12***a* formed in the inner surface of the housing **12** to properly align the container holder **131** within the housing **12** during assembly and to prevent and/or restrict rotational movement between the respective components **12**, **131**. The alignment ridge **131***n* shown in FIG. **4**D extends substantially completely along the axial length of the container holder **131**, in contrast to the alignment ridge **31***n*.

[0101] As with the container holder **31** shown in FIGS. **4**B-**4**C, the container holder **131** may include a plurality of lock ridges **133***c* on the flanges **133** that form a friction-fit with portion(s) of the housing **12**. As a more specific example and as shown in FIGS. **4**D and **4**E, the housing **12** includes a plurality of lock slots **12***c* that each receive respective lock ridges **133***c* of the container holder **131** to prevent and/or restrict relative movement between the respective components **12**, **131**. The lock ridges **133***c* may also give audible and/or tactile feedback to the user or an assembly worker as they snap into the corresponding lock slots **12***c*, thereby indicating to the assembler(s) that the respective components **12**, **131** are positioned as desired. Additionally, the container holder **131** may provide the same or similar advantages as those described above with respect to the container holder **31**.

[0102] In yet another exemplary design, the container holder may have a fixed state, rather than having arms that open and closed. As a more specific example, the container holder may have a proximal opening sufficiently sized to permit receipt of the syringe. The container holder may still have distally-located flanges for receiving and securing the shoulder portion of the syringe, particularly when the container holder is coupled with the injector housing.

[0103] FIGS. **4**F and **5**A show distal (FIG. **4**F) and proximal (FIG. **5**A) portions of the drug product container **20** and its interactions with various other components of the device **10**. For example, FIG. **4**F shows a partial cross-sectional view of a distal portion of the drug product container **20** positioned within the container holder **31**, with the shoulder portion **20***a* supported by the flanges **33**. As another example, FIG. **5**A shows a cross-sectional view of a proximal portion of the drug product container **20** positioned within the container holder **31** such that the drug product container flange **20***b* is positioned between the opposing surfaces **31***h*, **31***i* and within the opening **31***j*. The drug product container **20** shown in FIG. **5**A is further supported by the plunger guide **60**, such as a

flexible arm **60***a* of the plunger guide **60**. As a more specific example, the flexible arm **60***a* extends generally distally, and slightly radially inwardly, from a distal portion of the plunger guide **60***b*. As an even more specific example, the plunger guide **60** shown in FIG. **5**A includes a distal surface **60***b* that abuts the inwardly-protruding flanges **31***f*, **31***g* of the container holder **31**; the flexible arm **60***a* extends from the distal surface **60***b* in between the inwardly-protruding flanges **31***f*, **31***g*.

[0104] The flexible arm **60***a* may have a size, shape, and material type that promotes and/or permits flexure of the flexible arm **60***a*. As a more specific example, the flexible arm **60***a* is preferably flexible in the radial direction, so that when the drug product container **20** and the plunger guide **60** are inserted within the housing, the flexible arm **60***a* is aligned with the flange **20***b* and applies at least a gentle radial force (radially inwardly) on the drug product container **20**. In this configuration, the drug product container **20** is primarily supported at its distal portion (e.g., the shoulder portion **20***a*) by the container holder **31** and is also, at least secondarily, supported at its proximal portion (e.g., the flange portion **20***b*) by the plunger guide **60**. As a more specific example, the flexible arm **60***a* may provide radial support to the flange portion **20***b* and prevent and/or resist transverse movement of the drug product container **20** with respect to the housing **12**. Such a configuration may reduce or eliminate rattling noises from the device **10** and/or may facilitate proper alignment of the drug product container **20** during assembly. As another more specific example, the flexible arm **60***a* may provide axial support (e.g., in the distal direction) to prevent undesirable axial movement of the drug product container **20** with respect to the housing **12**. The device **10** may have any suitable number of flexible arms **60***a*, such as one, two, three, four, or more.

[0105] The container holder **31** may also include at least one support flange **31***r* that has a size, shape, and material type that promotes and/or permits flexure thereof. As a more specific example, the support flange **31***r* is preferably flexible in the radial direction, so that when the drug product container **20** and the container holder **31** are inserted within the housing, the support flange **31***r* is aligned with the body portion **20***g* of the drug product container and applies at least a gentle radial force (radially inwardly) on the drug product container **20**. In this configuration, the drug product container **20** is primarily supported at its distal portion (e.g., the shoulder portion **20***a*) by the container holder **31** and is also, at least secondarily, supported at a central or proximal region of the body portion **20***g* by the container holder **31**. As a more specific example, the support flange **31***r* may provide radial support to the drug product container **20** and prevent and/or resist transverse movement of the drug product container **20** with respect to the housing **12**. Such a configuration may reduce or eliminate rattling noises from the device **10** and/or may facilitate proper alignment of the drug product container **20** during assembly. As another more specific example, the support flange **31***r* may but is not required to provide axial support (e.g., in the distal direction) to prevent undesirable axial movement of the drug product container **20** with respect to the housing **12**. The device **10** may have any suitable number of support flanges **31***r*, such as one, two, three, four, or more. The container holder **31** shown in the figures includes four support flanges **31***r* that are equally spaced about the circumference thereof.

[0106] Although the flexible arm **60***a* and/or the support flanges **31***r* shown in the figures provides at least some support for the drug storage container **20**, the container holder substantially completely supports the drug storage container **20** with respect to the housing **12** by the distal end of the body portion **20***g* of the drug storage container **20**, as discussed above. As a more specific example, the flexible arm **60***a* and/or the support flanges **31***r* may provide little or no support along the longitudinal axis A and only provide support in a direction transverse to Axis A. As an even more specific example, the container holder **31** substantially completely supports the drug storage container **20** with respect to the housing **12** by the distal end of the body portion **20***g* of the drug storage container **20** for forces along the Axis A, such as forces experienced during the injection process.

[0107] As indicated above, the plunger guide **60** shown in FIG. **5**A includes a distal surface **60***b*

that abuts the inwardly-protruding flanges **31***f*, **31***g* of the container holder **31**. This configuration may help reduce or prevent radial movement of the container holder **31** within the housing **12**. For example, as shown in FIG. **5**A, the container holder includes an annular wall **31***p* that cooperates with the inwardly-protruding flanges **31***f*, **31***g* to define an annular seat for the distal surface **60***b* of the plunger guide **60**. The annular wall **31***p* may center the plunger guide **60** with respect to the container holder **31** and the drug product container **20** so that the plunger **26** is likewise aligned with those components **31**, **20**. The annular wall **31***p* may also reduce or prevent radial movement of the plunger guide **60** with respect to the housing **12**. This configuration may also help reduce or prevent axial movement of the container holder **31** within the housing **12**. For example, as shown in FIG. **2**, the plunger guide **60** extends from the rear end cap **23** to a mid-point of the device **10** where it abuts the container holder **31**. As a result, the container holder **31** is restricted from moving axially upward in FIG. **2** (i.e., proximally) by the plunger guide **60**. Furthermore, the rear end cap **23** may not be able to be installed unless the plunger guide **60** is properly axially and radially aligned with the container holder **31**, such as if the distal surface **60***b* is not abutting the inwardly-protruding flanges **31***f*, **31***g*.

[0108] As shown in FIGS. **5**B and **5**C, 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**. At least a portion of the distal end of the plunger guide **60** may be positioned radially between the plunger **26** and the releaser member **52**. As such, the plunger **26** may be disposed at least partially within the distal end of the plunger guide **60**, and the distal end of the plunger guide **60** may be disposed at least partially within the releaser member **52**, as illustrated in FIG. **2**. Further features and functions of the plunger guide **60** are discussed below.

[0109] As shown in FIG. **2**, the plunger guide **60** may be fixedly coupled with the housing such that the plunger guide **60** is substantially and/or generally immovable relative to the housing **12**. For example, and as shown in FIGS. **1**C and **5**B, the plunger guide includes a lock tab **60***f* that is sized, shaped, and aligned to be received within a lock key **12***f* formed within the housing **12**. As a more specific example, the plunger guide **60** and housing **12** each include a pair of respective components **60***f*, **12***f* that cooperate to prevent relative rotation between the plunger guide **60** and the housing **12**. Additionally or alternatively, annular ridges **60***g* formed on an outer surface of the plunger guide **60** may form a friction fit with the inner surface of the housing to resist or prevent rotation between the respective components **12**, **60**.

[0110] The plunger **26** (as best illustrated in FIGS. **2**, **3**A) 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. It is generally desirable to minimize a thickness of the annular wall **39**, to the extent possible and without compromising the integrity of the plunger **26**, so as to maximize an inner diameter of the plunger **26**. This allows a larger diameter plunger biasing member **50** to fit within the interior space of the plunger **26**, which, in turn, allows for a more powerful plunger biasing member **50**. As a more specific example, the thickness of the annular wall **39** may be less than 2 mm. As another more specific example, the thickness of the annular wall may be less than 1 mm. As another more specific example, the thickness of the annular wall may be less than 0.6 mm. As another more specific example, the thickness of the annular wall may be less than 0.3 mm. As another more specific example, the thickness of the annular wall may be less than 0.2 mm. As another more specific example, the thickness of the annular wall may be less than 0.1 mm. As another more specific example, the thickness of the annular wall may be less than 0.05 mm. 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 purposes of minimizing the thickness of the annular wall **39**. For example, a metal annular wall **39**

may have sufficient axial strength and/or buckle resistance for use in the device if the annular wall **39** thickness is greater than 0.05 mm. Conversely, a plastic annular wall **39** may have sufficient axial strength and/or buckle resistance for use in the device if the annular wall **39** thickness is greater than 1 mm.

[0111] The hollow rod **46** may additionally or alternatively facilitate and/or provide more flexibility in spring design. For example, it may be desirable or advantageous to use the device with different springs depending on the characteristics of the drug and/or the desired drug delivery profile. For example, a higher viscosity drug may require a spring with a higher spring rate and/or spring force and it thus may be desirable or advantageous to have flexibility in physical characteristics of the spring. As a more specific example, various physical characteristics of a spring may affect the spring rate, and thus the spring force, such as wire diameter of the spring (typically increasing the wire diameter increases the spring rate), mean diameter of the spring (typically increasing the mean diameter decreases the spring rate), the number of spring coils (typically increasing the number of coils increases the spring rate), and the spring material. These physical characteristics may be adjusted to deliver different spring rates, while also potentially adjusting the thickness of the hollow rod **46**, to maintain a constant or relatively constant outer diameter of the overall plunger **26** so as to keep constant the remaining parts of the device, such as the plunger guide **60** and the stopper **24**. The hollow rod **46** may additionally or alternatively facilitate and/or provide more longitudinal stability for the plunger biasing member **50**, such as by preventing or reducing buckling or other transverse movement.

[0112] The plunger biasing member **50** shown in the figures may include the following dimensions: 0.65 mm wire diameter, 5.40 mm outer diameter of the spring, and 80 to 86 number of coils (depending on pitch), but other suitable spring characteristics may be utilized. The plunger biasing member **50** shown in the figures may be formed of stainless steel strength 2300 n/mm, but other suitable materials may be utilized. The hollow rod **46** shown in the figures may include the following dimensions and materials: 63 mm length, 6 mm outer diameter, 0.20 mm wall thickness, and stainless steel strength 600 to 750 n/mm material, but other suitable dimensions and materials may be utilized.

[0113] 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**.

[0114] The plunger **26** may be constructed of multiple, interconnected pieces, or alternatively, have a one-piece construction. In the present embodiment, 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**, the hollow rod **46**, and the base **47** may be fixed relative to each other such that these components are immoveable relative to each other. The top ring **45**, the hollow rod **46**, and the base **47** may each have an annular construction and be centered about the longitudinal axis A. The top ring **45** and the 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 **46** that comes into contact with the stopper **24** to push the stopper **24** in the distal direction.

[0115] The top ring **45** may include one or more flanges or projections **48** which extend radially

outwardly from a central portion of the top ring **45**. Each of the projections **48** may include a distally facing camming surface **49**. As described below in more detail, the distally facing camming surface **49** may interact with a counterpart camming surface on a plunger guide **60** in order to release the plunger biasing member **50**. In some embodiments, the distally facing camming surface **49** may arranged at angle relative to, or is otherwise non-parallel to, an imaginary plane perpendicular to the longitudinal axis A.

[0116] 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** made 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.

[0117] The drug delivery device **10** may further include a guard mechanism for preventing contact with the insertion end **28** of the delivery member **16** when the drug delivery device **10** is not being used to administer an injection. The guard mechanism may include a guard member **32** moveably disposed at or near the distal end of the housing **12** adjacent to the opening **14**. The guard member **32** may have a hollow and generally tubular-shaped or cylindrical portion **32***a* centered about the longitudinal axis A, and may have a pair of arms **32***b* extending proximally from the cylindrical portion **32***a*. The guard member **32** further includes a distal end **32***c* that may generally include the cylindrical portion **32***a* and a proximal end **32***d* that may be defined by the arms **32***b*. The arms **32***b* may be substantially or completely received within the housing **12** such that no part thereof extends from the housing **12**. The cylindrical portion **32***a* may be at least partially and/or selectively received within the housing **12**. For example, the guard member **32** may be configured to move relative to the housing **12** such that portions of the guard member **32** are received within the housing **12** in some stages/states and are extending from the housing **12** in other stages/states, as is discussed below in more detail.

[0118] As one exemplary configuration, shown in FIGS. **2**, **4**E, and **6**, the arms **32***b* of the guide member **32** are radially spaced apart from each other along a circumference **32***g* of the guard **32** such that the arms **32***b* are able to slide between protruding sections of the annular collar **12***d* formed on the inner surface of the housing **12**. For example, that the length of the arc between respective edges of the arms **32***b* is at least slightly larger than an arcuate length of a protruding section of the annular collar **12***d* so that the arms are able to axially slide between the protruding sections of the annular collar **12***d* without contacting the collar.

[0119] As indicated above, the guard member **32** may be configured to move relative to the housing **12** between an extended position wherein at least a portion of the cylindrical portion **32***a* of the guard member **32** extends through the opening **14** in the housing **12** and a retracted position wherein a shorter length of the cylindrical portion **32***a* or no part of the cylindrical portion **32***a* extends through the opening **14** in the housing **12**. In other words, in the extended position, a length×of the cylindrical portion **32***a* extends from through the opening **14** in the housing **12** and in the retracted position, a length Y of the cylindrical portion **32***a* extends through the opening **14** in the housing **12**, wherein X is a value greater than Y. The length X may be any suitable number such as 10 mm, 8 mm, 6 mm, 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. FIGS. **1**C and **1**D illustrate an exemplary pre-injected configuration (FIG. **1**C) where the guard member **32** is an extended position **32***e* and the length of the exposed portion X of the guard member **32** may be

approximately 5 mm to 11 mm and an injection configuration (FIG. **1**D) where the guard member **32** is in a retracted position **32***f* and the length of the exposed portion Y of the guard member **32** is approximately 0 mm to 2 mm (such that the distal end **32***c* of the guard member **32** is flush with the opening **14** of the housing **12**). In one embodiment, the distance Y is greater than 0 (e.g. 1 mm) to help ensure the device **10** is able to be activated before the guard member is flush with the housing **12**.

[0120] The guard member **32** may also be configured to move in the opposite direction, namely from the retracted position to the extended position. When moving from the extended position to the retracted position, the guard member **32** may translate linearly in the proximal direction; and when moving from the retracted position to the extended position, the guard member **32** may translate linearly in the distal direction. In at least the extended position, the guard member **32** may extend beyond and surround the insertion end **28** of the delivery member **16**. As a further illustration, FIGS. **1**C and **2** show the guard member **32** in the extended position(and covered by the removable cap **19** in FIG. **2**). As discussed above, moving the guard member **32** from the extended position to the retracted position, e.g., by pressing the distal end of the guard member **32** against the patient's skin at the injection site, may result in the insertion end **28** of the delivery member **16** being inserted into the patient's skin.

[0121] During the injection process the guard member **32** may remain stationary with respect to the user's skin **5** while the housing **12** and several components disposed therein are moving with respect to the guard member **32** and the skin **5**. Nonetheless, this disclosure refers to moving, retracting, translating, and depressing the guard member **32**. These references and descriptions may be considered to refer to relative movement between the guard member **32** and the housing **12**, regardless of which component (guard member **32** or housing **12**) is moving with respect to the user's skin **5**.

[0122] The delivery device **10** may utilize inertial-driven design, rather than a spring-driven design, to insert the needle into the patient's subcutaneous tissue. As a more specific example, when the patient presses the distal end of the guard member **32** against the patient's skin at the injection site, the delivery device **10** housing **12** may advance toward the injection site. As the patient presses down a predetermined distance or with a predetermined force, the delivery device **10** achieves a quick release to harness the energy stored in the patient's muscles while compressing the needle cover and its spring to a defined release point. The release mechanism is designed such that the resulting needle insertion speed exceeds the patient's reaction speed, and the combination of this speed and the device's mass cause the needle to quickly and fully penetrate the skin to the subcutaneous depth. Compared to known injectors, where the entire primary container is moved forward with respect to the housing, this embodiment prevents relative movement between the drug storage container **20** and the housing and therefore may provide a simplified, more robust design.

[0123] In alternative embodiments, the drug storage container **20** may be moveably coupled to 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**.

[0124] In some embodiments, the guard member **32** may be rotationally fixed or rotationally restricted relative to the housing **12**. Therefore, although the guard member **32** may able to translate linearly relative to the housing **12**, the guard member **32** may be substantially or completely prevented from rotating relative to the housing **12**. As a more specific example, the cylindrical portion **32***a* of the guard member **32** may include a protrusion extending therefrom, for example a ridge **32***h*, that aligns with a corresponding feature on the inner surface of the housing **12**. For

example, the inner surface of the housing, adjacent to the distal end of the housing **12** may include a slot, a pair of adjacent ridges, or another component or set of components that cooperate with the ridge **32***h* to substantially or completely prevent rotation of the guard member **32**. This arrangement may also help align the respective components **32**, **12** with each other during assembly.

[0125] The device **10** may further include an extender biasing member **35** and a guard extension **37**. The guard extension **37** may be positioned proximal to the guard member **32**; and the extender biasing member **35** shown in the figures is positioned proximal to the guard extension **37**. The guard extension **37** may have a hollow and generally cylindrical or tubular shape centered about the longitudinal axis A. As a more specific example, the guard extension **37** may include a generally cylindrical body **37***a*. The guard extension **37** may also include arms **37***b* for receiving, supporting, and/or retaining a distal portion of the extender biasing member **35**. Furthermore, the guard extension **37** may be moveable in a linear direction along the longitudinal axis A relative to the housing **12**. In the present embodiment, the guard extension **37** is a separate structure from the guard member **32**. However, in alternative embodiments, the guard extension **37** and the guard member **32** may be integrally formed in one piece to define a single, monolithic structure. In such alternative embodiments, the proximal end of the guard member **32** may correspond to the guard extension **37**.

[0126] Similar to the guard member **32**, the guard extension **37** may be rotationally fixed relative to the housing **12**. Therefore, although the guard extension **37** may able to translate linearly relative to the housing **12**, the guard extension **37** may be prevented from rotating relative to the housing **12**. To achieve this effect, in some embodiments the guard extension **37** may cooperate with the plunger guide **60** to restrict or prevent rotation between the respective components **37**, **60**. As a result, and because the plunger guide **60** is fixedly connected with the housing **12**, the guard extension **37** may be rotationally fixed to the housing **12** through the plunger guide **60**. For example, the plunger guide **60** may include a longitudinal ridge **60***c* near a distal portion of the plunger guide **60**. The ridge may be received within a longitudinal channel on the inside surface of the guard extension **37** and/or a pair or corresponding features that cooperate to receive the ridge **60***c*. In alternative embodiments, the ridge-and-slot arrangement may be reversed, such that the guard extension **37** has one or more radially inwardly extending ridges and plunger guide has one or more slots or other recesses to matingly or snugly receive the one or more ridges. As yet another alternative, the guard extension **37** may include an anti-rotation feature that mates with a corresponding feature on the inner surface of the housing **12**.

[0127] The guard extension **37** and/or the releaser member **52** may have axial travel limits that limit the distance they are able to travel in the distal direction. For example, as illustrated in FIG. **6**C, the plunger guide **60** may include and axial ridge **60***c* formed on the outer surface and positioned adjacent to a distal portion of the plunger guide **60**. A distally facing surface **52***j* of the releaser member **52** may abut a proximally facing surface **60***d* defined by the axial ridge **60***c*, thereby defining the distal-most point of travel for the releaser member **52**. The releaser member **52** also may include the locking flange **52***a* that in turn limits the distal travel of the guard extension **37**. For example, the locking ridge **52***a* may abut an annular collar **37***d* of the guard extension **37** to define the distal-most point of travel for the guard extension **37**. The axial ridge **60***c* and the locking ridge **52***a* shown in the figures do not necessarily limit travel of the releaser member **52** and the guard extension **37** in the proximal direction, just the distal direction.

[0128] As is best illustrated in FIG. **2**, the extender biasing member **35** is positioned between and in contact with the guard extension **37** and a releaser member **52**. The extender biasing member **35** may be configured to bias or urge the guard extension **37** in the distal direction and/or bias or urge the releaser member **52** in the proximal direction. In the device **10** shown in FIG. **2**, which is in the pre-delivery or storage state, the extender biasing member **35** is initially in an energized state (e.g., compressed). In other words, when the device **10** is in the pre-delivery state, as shown in FIG. **2**, the extender biasing member **35** exerts a distal direction (downward) biasing force on the guard

extension **37** and a proximal direction (upward) biasing force on the releaser member **52**.
[0129] During operation of the device, a user may cause the guard member **32** to translate (with respect to the housing **12**) in the proximal direction by pressing the guard member **32** against the injection site. In doing so, the guard member **32** will move towards the guard extension **37** and close the gap **37***g* therebetween (FIG. **2**). Once the gap **37***g* is eliminated, the guard member **32** and the guard extension **37** move jointly in the proximal direction until, for example, the guard member **32** reaches the retracted position **32***f*. When the injection is complete and the drug delivery device **10** is lifted off of the injection site, the extender biasing member **35** may urge the guard extension **37** so that the guard extension **37** and the guard member **32** move jointly in the distal direction. This motion(and/or a biasing force from lock ring biasing member **51**) returns the guard member **32** to the extended position **32***e*, which has the effect of covering the insertion end **28** of the delivery member **16**. In some embodiments, the extender biasing member **35** may include a compression spring (e.g., a helical compression spring). Furthermore, in embodiments where the plunger biasing member **50** also includes a compression spring, the extender biasing member **35** may disposed around and/or have a larger diameter than the plunger biasing member **50**.
[0130] However, in some alternative embodiments, the extender biasing member **35** may be in non-energized (natural) state when the device is in a pre-delivery state. In these embodiments, the biasing member **35** may become compressed or energized upon deflection of the guard member **32** in the proximal direction.
[0131] After drug delivery is complete and the guard member **32** has been re-deployed to the extended position, it may be desirable to lock the guard member **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, 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 member **32**, in order to lock the guard member **32** in the extended position once the guard member **32** has moved from the retracted position to the extended position, as will be discussed in more detail below.
[0132] As discussed above, the plunger biasing member **50** may be disposed at least partially within the plunger **26**, and may have a distal end abutting against a proximally facing inner surface of the plunger **26** and/or may be fixedly attached to an inner surface of the plunger **26**. So that the plunger biasing member **50** may be received within the plunger **26**, an outer diameter or other dimension of the plunger biasing member **50** may be equal to or less than an inner diameter of the top ring **45** and/or equal to or less than an inner diameter of the hollow rod **46**. In some embodiments, the distal end of the plunger biasing member **50** may abut against a proximally facing inner surface of the base **47** of the plunger **26**. Furthermore, as best illustrated in FIGS. **2** and **3**A, a proximal end **50***a* of the plunger biasing member **50** may abut against a distally facing surface **38***a* of the plunger biasing member seat **38**. The plunger biasing member seat **38** may be fixedly attached to the rear housing **27** such that the plunger biasing member seat **38** provides a stationary surface for the plunger biasing member **50** to push off of. For example, as shown in FIGS. **3**A and **5**B, the plunger seat **38** may include flanges **38***b* that are received within openings **60***h* formed in a proximal portion of the plunger guide, thereby fixedly coupling the plunger seat to the plunger guide **60**. 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** is 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 a as a result the delivery member **16**, is substantially or completely

fixedly coupled with respect to the housing **12**. Rather, 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).

[0133] Referring to FIGS. **7**A and **7**B, of 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 guard extension **37**. As also illustrated in FIG. **2**, the releaser member **52** is also radially positioned between the guard extension **37** and the plunger guide **60**. Furthermore, the extender biasing member **35** may be axially positioned between the releaser member **52** and the guard extension **37** and may be radially arranged around the releaser member **52**. Generally, the releaser member **52** is configured to: (1) operably couple the guard member **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**.

[0134] The channel surfaces **52***b* are each configured to receive the projections **48** of the top ring **45** and permit axial movement of the plunger **26** with respect to the releaser member **52** but to resist or prevent rotational movement between the plunger **26** and the releaser member **52**. As shown in the figures, although the channel surface **52** extends adjacent to the inner surface of the releaser member **52**, the channel surface **52** does not have an arcuate shape and instead has a generally squared-off shape(as best illustrated in FIGS. **7**B and **10**A).

[0135] The releaser member **52** includes a channel surface **52***b* that extends proximally past the proximal-most (e.g., top) surface of the tubular body of the releaser member **52**. For example, the releaser member **52** includes a proximally facing contact surface **52***d* for end-of-dose notification, which will be described in more detail below, and the channel surfaces **52***b* each extend past the contact surface **52** so as to provide a continuous path with respect for the top ring **45** while also permitting a sufficient gap between the proximally facing contact surface **52***d* and the corresponding surface involved in end-of-dose notification.

[0136] The releaser member **52** may be configured to rotate relative to the housing **12** and/or translate linearly relative to the housing **12**, depending on the stage of operation of the drug delivery device **10**. Initial rotation of the releaser member **52** associated with activation may be powered by the plunger biasing member **50** and/or the extender biasing member **35**; whereas later rotation of the releaser member **52** associated with generation of the end-of-dose signal may be powered solely by the extender biasing member **35**. Any linear translation of the releaser member **52** without rotation may be powered solely by the extender 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.

[0137] Having described the general configuration of the drug delivery device **10**, a method of using the drug delivery device **10** to perform an injection will now be described with reference to FIGS. **9**A-**12**C. 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 front housing **25**. As a result of this motion, the gripper **13** may pull and detach the 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 member **32** at this stage because the guard member **32** is arranged in the 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 member **32** against the injection site. The force applied by the user will overcome the biasing force of the extender biasing member **35** and the biasing force of the lock ring biasing member **51**, thereby

causing the guard member **32** to retract into the opening **14** moving from the extended position to the retracted position in the proximal direction. The delivery member **16** remains stationary relative to the housing **12** during the retracting movement of the guard member **32**.

[0138] Several of the device components include various features, surfaces, and openings for interacting with and controlling the release movement of the plunger **26** (e.g. the injection sequence). Generally, the injection sequence begins with retraction/axial movement of the guard member **32** in the proximal direction (upward in FIG. **2**), which causes axial movement of the guard extension **37**, which unlocks the releaser member **52**. Once the releaser member **52** is unlocked (e.g. first stage of travel), the plunger **26** and the plunger biasing member **50** urge the releaser member **52** to rotate clockwise and permit axial movement of the plunger **26** (in the distal direction, downward in FIG. **2**). The plunger then urges the stopper **24** in the distal direction, thereby urging the drug **22** from the drug product container **20** and out of the delivery member **16**. Once the plunger has reached a certain point along the axial length of the device, movement of the releaser member **52** is further unlocked (e.g. second stage of travel) and the releaser travels in the proximal direction (upward in FIG. **2**) and into contact with the plunger guide **60**, thereby generating an end-of-dose indication (such as an audible click). The injection sequence will now be described in more detail.

[0139] The pre-injection stage is shown in FIGS. **2**, **9**A, **10**, and **11**A. Movement of the guard member **32** from the extended position to the retracted position may cause several actions to occur. Because the delivery member **16** remains stationary relative to the housing **12** during retraction of the guard member **32**, the insertion end **28** of the delivery member **16** is caused to extend through an opening in the distal end of the guard member **32**, thereby piercing the patient's skin at the injection site and penetrating into the patient's subcutaneous tissue. In addition, retraction of the guard member **32** may also activate the drive mechanism **30** to expel the drug **22** from the drug storage container **20**, as described below in more detail.

[0140] In the pre-delivery state prior to retraction of the needle guard **32**, the plunger **26** and the releaser member **52** each may be arranged in a respective initial rotational position, as illustrated in FIGS. **9**A, **10**, and **11**A. The plunger biasing member **50** may be in an energized state. As a consequence, the plunger biasing member **50** may exert a distally directed biasing force on the plunger **26** which urges the distally facing camming surface **49** against the proximally facing camming surface **60***j*. A resulting camming action may urge the plunger **26** to rotate in the clockwise direction. Despite these biasing force(s), neither the releaser member **52** nor the plunger **26** rotates in the pre-delivery state. This is because the releaser member **52** and the plunger are rotationally fixed in the pre-injection state. Accordingly, the releaser member **52**, the plunger guide **60**, the guard extension **37**, and the housing **12** work in conjunction with one another to retain the plunger biasing member **50** in the energized state prior to retraction of the guard member **32**, as is now described in more detail.

[0141] As best shown in FIG. **2**, as the guard member **32** travels in the proximal direction (upward in FIG. **2**), the proximal end **32***d* of the guard member **32** contacts a distally-facing surface of the guard extension **37** and urges the guard extension in the proximal direction. As shown in FIGS. **6**B and **7**A the inner surface of the guard extension **37** annular wall includes a locking flange **37***c* and the outer annular surface of the releaser member **52** a corresponding locking flange **52***a*. When the device is in the pre-injection stage, as shown in FIGS. **2**, **9**A, **10**A, and **11**A, the guard extension **37** locking flange **37***c* engages the releaser member **52** locking flange **52***a*, thereby rotationally locking the releaser member **52** (as best illustrated in FIG. **11**A). At this point in the sequence, the distally facing camming surface **49** of top ring **45** of the plunger **26** is abutting against a proximally facing camming surface **60***j* of the plunger guide **60** such that the plunger **26** is restrained from axial travel due to this interaction (best illustrated in FIGS. **9**A and **10**A). The distally facing camming surface **49** and/or the proximally facing camming surface **60***j* includes a sloped surface to promote relative movement of the plunger **26** top ring **45** in the direction of arrow **60***k* in FIGS. **9**A and **10**A

(clockwise). For example, the distally facing camming surface **49** has a slope **60***m* of approximately 10 degrees (best illustrates in FIGS. **9**B and **9**C) but may have any suitable slope such as 9 to 11 degrees, 8 to 12 degrees, 7 to 13 degrees, 6 to 14 degrees, 5 to 15 degrees, 4 to 16 degrees, or any other suitable slope. Additionally or alternatively, the distally facing camming surface **49** of top ring **45** may have a slope **49***a* of approximately 10 degrees but may have any suitable slope such as 9 to 11 degrees, 8 to 12 degrees, 7 to 13 degrees, 6 to 14 degrees, 5 to 15 degrees, 4 to 16 degrees, or any other suitable slope. The slope(s) on one or more of the respective surfaces **60***j*, **49** causes the axial force from the plunger biasing member **50** to generate a force in the transverse direction, thereby urging the plunger **26** top ring **45** in the clockwise direction **60***k*. However, as discussed above, the releaser member **52** resists or prevents rotational movement between the releaser member **52** and the plunger while the top ring **45** is positioned within and/or contacting the channel surface **52***b*. As a result, as long as the guard extension **37** is rotationally locking the releaser member **52** (as shown in FIGS. **2**, **9**A, **10**A, and **11**A), then the top ring **45** will remain rotationally locked by the channel surface **52***b* and axially locked by the proximally facing camming surface **60***j*.

[0142] The unlocking stage is shown in FIG. **11**B, where the guard extension **37** translates in the proximal direction until the guard extension **37** locking flange **37***c* no longer engages the releaser member **52** locking flange **52***a* and the releaser is no longer rotationally locked. At this stage in the injection sequence, two things happen simultaneously or near simultaneously: (1) the guard biasing member **35** urges the releaser member **52** in the clockwise direction (shown in FIG. **9**B) and upward due to a camming surface on one or both of the inner surface of the releaser member **52** (generally aligned with numeral **52***c* labeled in FIGS. **9**C and **7**B, but on the inner surface of the releaser member **52** rather than the outer surface as indicated by **52***c*) or the outer surface of the plunger guide **60** (such as rib **60***n*, FIG. **5**B) that translates the axial force from the guard biasing member **35** into a transverse (clockwise) force and causes the releaser member **52** to rotate clockwise and move upward (proximally) and (2) the plunger biasing member **50** urges the top ring **45** in the clockwise direction and downward (distally) due to the camming action between surfaces **49**, **60***j* of the plunger **26** and the plunger guide **60** thereby causing the plunger **26** to move clockwise and slightly downward along ramped surface **60***j*. In other words, the releaser member **52** and the plunger **26** top ring **45** are both rotating clockwise at the same time or substantially the same time, due to forces from respective biasing members **35**, **50**. This sliding motion between surfaces **49**, **60***j* of the plunger **26** and the plunger guide **60** results in rotation, as well as linear translation (not unlike a spiral pathway). Accordingly, the plunger guide **60** may function as a cam and the plunger rod **26** the cam follower.

[0143] The unlocked stage is shown in FIGS. **9**B, **10**B, and **11**C. In this stage, the distally facing camming surface **49** of the top ring **45** has cleared the proximally facing camming surface **60***j* of the plunger guide **60** such that the top ring **45** (and thus the plunger **26**) is no longer axially restrained by the plunger guide **60**. As a result, the plunger biasing member **50** urges the plunger **26** axially in the distal direction.

[0144] The downward stroke stage is shown in FIGS. **9**C, **10**C, and **12**A. At this point in FIGS. **9**C, **10**C, and **12**A, the top ring **45** is still visible near the proximal portion of the plunger guide **60**, but it will quickly travel along a longitudinal slot **86** formed in the plunger guide **60** and the channel surface **52***b*. During this stage, the plunger **26** top ring **45** is traveling along both the channel surface **52***b* of the releaser member **52** and the longitudinal slot **86** of the plunger guide **60**, thereby preventing rotation between any of the three components (**26**, **52**, **60**). As a more specific example, because the plunger guide **60** is rotationally fixed with respect to the housing **12**, while the top ring **45** is positioned within both the channel surface **52***b* and the longitudinal slot **86**, the releaser member **52** is unable to rotate. Also during this stage, as the plunger **26** travels distally, the gap **18** between the base **47** of the plunger **26** and the stopper **24** shrinks and the base **47** contacts the stopper **24**. The device **10** is designed such that plunger **26** is traveling with a force sufficient to

drive the stopper **24** in the distal direction and urge the drug **22** from the delivery member **16**. At the same time, the device **10** is also designed such as to reduce or eliminate the likelihood of glass breakage, undesirable forces acting on the patient, and/or undesirable impact vibration or sound due to interaction between the base **47** and the stopper **24**. For example, the plunger biasing member **50** design parameters may be designed to meet these two sets of design goals. As another example, a damping component may be positioned between the base **47** and the stopper **24** or in another location in the device **10** to dampen the forces between the base **47** and the stopper **24**. For example, the base **47** may include an elastomeric component, section, or other damping feature. Additionally or alternatively, the stopper **24** may be formed of an elastomeric material that includes inherent damping properties. Additionally or alternatively, the stopper **24** may include an additional elastomeric component, section, or other damping feature.

[0145] In some embodiments, the camming action between the distally facing camming surface **49** on the projection **48** and the proximally facing camming surface **60***j* of the plunger guide **60** may provide a damping effect. More particularly, a sliding friction between these two surfaces may be selected to slow initial expansion of the plunger biasing member **50**. As a consequence, the velocity of the plunger **26** may be reduced during the initial expansion of the plunger biasing member **50**, as compared to free uninhibited expansion of the plunger biasing member **50**. The reduced velocity of the plunger **26** may cause the plunger **26** to strike the stopper **24** with less force, which reduces the chances of structural damage to the drug storage container **20** and/or facilitates a more comfortable injection for the user.

[0146] The end-of-dose stage is shown in FIGS. **12**B and **12**C. As discussed above, during the downward stroke stage, while the top ring **45** is positioned within the channel surface **52***b* and the longitudinal slot **86**, the releaser member **52** is unable to rotate with respect to the plunger guide **60**. However, in the end-of-dose initiation stage shown in FIG. **12**B, the top ring **45** in some embodiments may clear the distal end of the releaser member **52** and no longer restricts or prevents rotation of the releaser member **52**. As a more specific example, as shown in the bottom portion of FIG. **12**B, as the top ring **45** exits the channel surface **52***b* and/or a distal surface **52***d* of the releaser, the releaser member **52** is no longer rotationally constrained by the top ring **45** and the releaser member **52** is urged upward by the guard biasing member **35**. As a result of the upward force of the guard biasing member **35** and camming surfaces, the releaser member **52** rotates clockwise while it moves upward in a spiral like path and a proximal facing surface **52***d* of the releaser member **52** contacts a distal facing surface **60***p* of the plunger guide **60**, thereby making an audible click sound. As a more specific example, FIG. **12**B shows a gap **90** between the respective surfaces **52***d*, **60***p*, but that gap **90** is then eliminated when the releaser member **52** travels proximally, as shown in FIG. **12**C. The length of the channel surface **52***b* and plunger **26** may be designed so that the top ring **45** exits the channel surface **52***b* as the stopper **24** reaches a desired point of travel within the drug storage container **20**, such as its end of travel near the distal end of the drug storage container **20**.

[0147] As a more specific example of the camming surface arrangement between the releaser member **52** and the plunger guide **60**, and as discussed above, the rib **60***n* of the plunger guide **60** is aligned with the inner surface of the releaser member **52** that is indicated by **52***c* in FIG. **7**A and in FIG. **7**B (but on the inner surface rather than the outer surface as indicated by **52***c*). The rib **60***n* has a sloped surface to help facilitate and/or promote relative rotation between the components **52**, **60**. More specifically, the urging force of the guard biasing member **35**, combined with the sloped surface of the rib **60***n*, creates a rotational force (e.g., torque) and causes the releaser member **52** to rotate with respect to the plunger guide **60**. During the first stage of releaser member **52** rotation (e.g., the unlocking stage shown in FIG. **11**B), the rib **60***n* travels along a first section of the inner camming surface **52***c* of the releaser member **52**, such as the first section **52***f* shown in FIG. **7**B. During the second stage of releaser member **52** rotation (e.g., the end-of-dose stage shown in FIGS. **12**B and **12**C), the rib **60***n* travels along a second section of the inner camming surface **52***c* of the

releaser member **52** such as the second section **52***g* shown in FIG. **7**B. As is visible in FIG. **7**B, the second section **52***g* includes a pocket **52***h* that is able to receive the rib **60***n* and permit the releaser member **52** to quickly move proximally towards the plunger guide **60** and cause the end-of-dose audible click. In summary, during the end-of-dose stage, the top ring **45** clears the channel surface **52***b* of the releaser member **52** and the guard biasing member **35** and the rib **60***n* cause the releaser member **52** to rotate and move upwards, ending with a quick upward (proximal) movement of the releaser member **52** into contact with the plunger guide **60** as the rib **60***n* moves into the pocket **52***h*.

[0148] Once the patient and/or health care provider hears the audible sound, 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 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-dose position.

[0149] As described above, in addition to its retaining function, the releaser member **52** may also be used to generate an audible signal indicating to the user that drug delivery or dosing is complete. This dual-function role may reduce part quantity and/or design complexity. Alternatively, the releaser member **52** does not need to have this indicator function. In alternative embodiments, the indicator may be defined by a structure that is separate from but rigidly attached to the releaser member **52**.

[0150] While the foregoing descriptions may utilize the extender biasing member **35** to provide the actuation energy needed generating the end-of-dose signal, alternative embodiments may utilize a biasing member that is separate from extender biasing member **35** for this purpose. In certain such embodiments, this additional biasing member may have a distal end fixed relative to the housing **12** and a proximal end abutting against a distally facing surface of the releaser member **52**. As such, the biasing member may push off of the housing **12** to exert a biasing force in the proximal direction against the releaser member **52**. Furthermore, this biasing member may operate independently of the plunger biasing member **50** and the extender biasing member **35**.

[0151] In any case, once the user receives some assurance that drug delivery is complete, the user may then lift the drug delivery deice **10** off of the injection site. With nothing to resist it, the extender biasing member **35** may push the guard member **32** from the retracted position to the extended position to cover the insertion end **28** of the delivery member **16**. In some embodiments, this movement of the guard member **32** may cause the lock ring **40** to rotate to a position where it prevents subsequent retraction of the guard member **32**.

[0152] For example, as discussed above, in some embodiments of the drug delivery device **10** may include a lock ring **40** configured to lock the guard member **32** in the extended position once the guard member **32** has moved from the retracted position to the extended position In the present embodiment, the lock ring **40** is centered and rotates about the longitudinal axis A. As illustrated in FIG. **2**, a proximal end of the lock ring **40** may be in contact with the a portion of the housing **12** and the distal end of the lock ring **40** may be disposed at least partially within the guard member **32**. The lock ring 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 member **32**. The lock ring biasing member **51** may initially be in a compressed or energized state such that it biases the lock ring **40** and the guard member **32** away from each other. As such, the lock ring biasing

member **51** may exert a biasing force urging the guard member **32** toward the extended position, as well as exert a biasing force urging the proximal end of the lock ring **40** against a portion of the housing **12**, such as the annular collar **12***d*. In some embodiments, the lock ring biasing member **51** may include a compression spring (e.g., a helical compression spring).

[0153] The lock ring **40** may also serve to provide an initial resistance to movement of the guard member **32**. As discussed above, the device **10** may be inserted into the patient by utilizing, harness, or otherwise taking advantage of inertial forces. The lock ring **40** and/or other components may provide an initial resistance to movement of the guard member **32** to build-up the user inputted force, as is discussed in more detail below.

[0154] FIG. **13** shows a perspective view of the lock ring **40**. In the example shown in FIG. **13**, the lock ring **40** includes a camming surface **40***a* that is non-parallel to the axis A and configured to convert translational movement of the shield guard **32** into rotational movement of the lock ring **40**. As a more specific example, the camming surface **40***a* shown in FIG. **13** is at an angle **40***d* to the axis A of approximately-30 degrees. Any suitable angle may be utilized, such as −10 to −80 degrees, −20 to −70 degrees, −20 to −60 degrees, −20 to −50 degrees, −20 to −40 degrees, −25 to −35 degrees, or any other suitable angle. The angle **40***d* may be a positive number as well (such that the angled surface is flipped around the axis A), but such as configuration would cause the lock ring **40** to rotate in the opposite direction. In such a case, any suitable angle may be utilized, such as 10 to 80 degrees, 20 to 70 degrees, 20 to 60 degrees, 20 to 50 degrees, 20 to 40 degrees, 25 to 35 degrees, or any other suitable angle.

[0155] In the example shown in FIG. **13**, the lock ring **40** includes a locking arm **40***b* that may be a generally cantilevered arm extending(along a circumference of the lock ring **40**) from a body portion of the lock ring **40**. The locking arm **40***b* may include a ridge **40***c* extending transversely to the body portion of the lock ring **40** (i.e. outwardly and non-parallel to the axis A).

[0156] FIG. **14** shows the lock ring **40** along with other various components of the device in a pre-deflection stage (e.g., before the guard member **32** has deflected axially in the proximal direction). For example, FIG. **14** shows a distal portion of the housing **12** that is in partial cross-sectional view for illustrative purposes, the guard member **32** in translucent form and partially cut-away for illustrative purposes, the lock ring **40**, and a portion of the housing inner collar **12***d*. The guard member **32** includes a plurality of ribs formed on the annular inner surface thereof. These ribs are shown in FIG. **14**, but portions of the annular surface itself have been cut away for illustrative purposes. Similarly, although portions of the housing **12** have been cut away for illustrative purposes, the annular collar **12***d* formed on the inner surface of the housing **12** is visible in FIG. **14**. When the device **10** is in the pre-deflection stage(as shown in FIG. **14**), the ridge **40***c* is adjacent to an inertial rib **32***k* formed on the inner annular surface of the guard member **32**. As a more specific example, when the device **10** is in the pre-deflection stage, the ridge **40***c* is disposed to the left of the inertial rib **32***k* such that the lock ring **40** generally resists rotation(and thereby resists axial deflection of the guard member **32**) until the ridge **40***c* is able to move past the inertial rib **32***k* (i.e. to clear the inertial rib **32***k*). This arrangement is discussed in more detail below.

[0157] FIGS. **15**A and **15**B show views from different angles(approximately a 90 degrees apart from each other) when the device is in the initial deflection stage just after the guard member **32** has been released from engagement with the locking arm **40***b*. As a more specific example, the lock ring **40** has rotated such that the ridge **40***c* has just cleared locking rib **32***k*, thereby allowing the guard member **32** to more freely deflect (in the proximal direction). At this point in the sequence, the injection sequence likely has not been activated. For example, the plunger biasing member **50** likely has not yet been released, as the housing **12** has not yet traveled distally enough for the delivery member **16** to pierce the user's tissue.

[0158] In order for the components of the device to move from the stage shown in FIG. **14** to the stage shown in FIGS. **15**A and **15**B, two main events have occurred generally simultaneously with each other: initial rotation of the lock ring **40** and release from the locking arm **40***b*. With respect to

the initial rotation, as shown in FIG. **15**B, the lock ring camming surface **40***a* is generally aligned with camming rib **32***j* to convert translational movement of the shield guard **32** into rotational movement of the lock ring **40**. As a more specific example, as the shield guard is retracted the proximally facing top surface of the camming rib **32***j* applies an axial upward force on the camming surface **40***a*. As a more specific example, the angle of the camming surface **40***a* with respect to the axis A causes the upward force from the camming rib **32***j* to have an axial component(along axis A) as well as a rotational component (transverse to axis A), thereby rotating the lock ring **40**. In other words, in both the stage shown in FIG. **14** and the stage shown in FIGS. **15**A and **15**B, deflection (retraction) of the guard member **32** causes rotation of the lock ring **40**. At the same time that camming rib **32***j* is urging the lock ring **40** to rotate to the right (i.e. counter-clockwise when viewed from the top of FIG. **15**B), the locking arm **40***b* may be generally resisting such movement. For example, when the guard member **32** is depressed, it moves from the position shown in FIG. **14** to the position shown in FIGS. **15**A and **15**B. As a more specific example, when the device **10** is in position shown in FIG. **14**, the ridge **40***c* is disposed to the left of the inertial rib **32***k* such that the lock ring **40** is unable to rotate past a certain point until the ridge **40***c* is able to clear the inertial rib **32***k*. The ridge **40***c* may be able to clear the inertial rib **32***k* via radially inward deflection of the locking arm **40***b*, as is shown in FIG. **15**A. In such a design, the flex of the locking arm **40***b* at least partially determines the force required for the ridge **40***c* to clear the inertial rib **32***k*. In other words, the flex of the locking arm **40***b* at least partially determines the force required to deflect the guard member **32** sufficiently to activate the injection process. The angle of the ridge **40***c* with respect to the circumference of the lock ring **40** may also, in part, determine the force required to deflect the guard member **32** sufficiently to activate the injection process. Additionally, the degree of rotation that the lock ring **40** must undergo for the ridge **40***c* to clear the inertial rib **32***k* at least partially determines the distance that the guard member **32** will translate(axially) before the locking arm **40***b* “releases” the guard member **32**.

[0159] During operation, when the patient presses the distal end of the guard member **32** against the patient's skin at the injection site, the delivery device **10** housing **12** may advance toward the injection site by a relatively small distance (e.g. 2-4 mm). The patient may then feel resistance between the inertial rib **32***k* and the ridge **40***c*. As the patient presses down with more force, the ridge **40***c* will clear the inertial rib **32***k* and the delivery device **10** will achieve a quick release to harness the energy stored in the patient's muscles while compressing the needle cover and its spring to a defined release point. The release mechanism, such as the above-described flex of the locking arm **40***b*, the degree of rotation required to clear the inertial rib **32**, and other parameters, may be designed such that when the ridge **40***c* clears the inertial rib **32***k*, the resulting needle insertion speed exceeds the patient's reaction speed, and the combination of this speed and the device's mass cause the needle to quickly and fully penetrate the skin to the subcutaneous depth. In other words, once the guard member **32** reaches the position shown in FIGS. **15**A and **15**B, the resistance to depressing the guard member drops significantly so that the needle is inserted before the patient is able to halt the insertion process. As a more specific example, at this stage in the insertion process, the primary resistance to deflection of the guard member **32** that is attributable to the components in the distal portion of the device is from the lock ring biasing member **51**, but that resistance is significantly lower than that provided by the locking arm **40***b*. Also, of note, the user may still feel resistance against deflection of the guard member **32** that is attributable to other subcomponents in the device, such as activation of the drive mechanism **30**. Even though the insertion process occurs very quickly from this point forward, the subsequent stages will be examined in detail in the figures and the below text.

[0160] FIGS. **16**A and **16**B show views from different angles(approximately a 90 degrees apart from each other) when the device is in the continued downward travel stage(a later point in time than FIGS. **15**A and **15**B, where the housing has moved further in the distal direction and the guard member **32** has been further retracted). At the point in the sequence shown in FIGS. **16**A and **16**B,

the injection sequence may or may not have begun, depending on the desired release parameters such as needle length, desired insertion depth, distance between the guard member **32** and the tip of the needle.

[0161] As shown in FIG. **16**A, at this point in the sequence, the camming rib **32***j* of the guard member **32** clears or is about to clear the camming surface **40***a* so that the guard member **32** is able to deflect without rotating the lock ring **40**. Additionally or alternatively, a ramped surface **40***e* of the lock ring **40** may engage a ramped surface **12***g* of the housing **12** (that may be defined by the annular collar **12***d*, similar or the same as the ramped surface **412***g* in FIG. **25**); this interaction between the respective surfaces **40***e*, **12***g* may also promote rotation of the lock ring **40** until it reaches the point shown in FIGS. **16**A and **16**B. Additionally or alternatively, at this stage of the insertion, a stop ridge **40***f* of the lock ring **40** engages a stop rib **32***n* and limits rotation of the lock ring **40**. However, as discussed above, at this stage the guard member **32** is able to deflect without requiring or causing further rotation of the lock ring **40**. More specifically, as shown in FIGS. **16**B and **17**, the adjacent ribs (the stop rib **32***n* and the camming rib **32***j*) extend between the adjacent components of the lock ring **40** (the stop ridge **40***f* and the camming surface **40***a*) so that the guard member **32** is able to deflect with respect to the housing **12**.

[0162] FIG. **17** shows a view when the device is in the final insertion stage, when the guard member is fully or nearly fully retracted. At this point in the sequence, the injection sequence likely has been activated. For example, the plunger biasing member **50** likely has been released and the delivery member **16** has been inserted into the user's tissue. Additionally, at this point in the sequence, the guard member **32** is at or near its fully retracted position with respect to the housing **12** and the device **10** is still being held against the patient's skin. The user will preferably hold the device **10** in this position until at least the time when the drug delivery process is complete (i.e., when the full dose of the drug **22** has been delivered to the patient) and the end-of-dose notification indicates that the dose is complete. Of note, for illustrative purposed, the guard member **32** shown in FIG. **17** has portions cut-away and FIG. **17** does not show the housing **12** (including the annular collar) or the drug storage container **20**.

[0163] FIGS. **18**A and **18**B shows the device **10** in a locked-out configuration, when the guard member **32** is in the fully extended position (FIG. **18**A) or near-fully extended position (FIG. **18**B). As a more specific example, the stop rib **32***n* and the camming rib **32***j* of the guard member **32** are aligned with the stop ridge **40***f* to limit and/or prevent deflection of the guard member **32** in the proximal direction. As another more specific example, the guard member **32** is only able to travel in the proximal direction by the distance shown by gap **91** in FIG. **18**A so that the guard member **32** is unable to be moved axially in the proximal direction by a distance sufficient to expose the delivery member **16**. In other words, the guard member **32** is locked in a guarded position annularly surrounding the needle and minimizing or preventing inadvertent needle sticks.

[0164] In some embodiments, prior to removal of the removable cap **19**, the gripper **13** may be configured to prevent deflection of the locking arm **40***b*. As an example, an outer surface of the gripper **13** may be configured to abut against an inner surface of the locking arm **40***b* to prevent radially inward deflection of the locking arm **40***b* prior to removal of the removable cap **19**. This configuration may reduce the possibility of unintended lockout caused by vibrations or sudden movements during transport or storage of the drug delivery device **10** prior to use. When the removable cap **19** with the gripper **13** is removed, the locking arm **40***b* may be allowed to deflect in the manner described above.

[0165] The lock ring **40** and the housing **12** have respective stop surfaces that abut each other and prevent rotation therebetween. For example, the lock ring **40** may have stop surfaces **40***g* and **40***h* (FIGS. **18**A, **13**) that abut stop surfaces **12***j*, **12***k* (FIG. **18**A) of the annular collar **12***d*. The respective stop surfaces **40***g*, **40***h* of the lock ring **40** and the respective stop surfaces **12***j*, **12***k* of the annular collar **12***d* may be stepped surfaces to prevent or resist rotation between the lock ring **40** and the housing **12**. The lock ring biasing member **51** may urge the lock ring **40** in the proximal

direction and/or the guard member **32** in the distal direction to retain the lock ring **40** in place as shown in FIGS. **18**A and **18**B, namely abutting the annular collar **12***d*.

[0166] The circular cross-section of the housing **12** may make it prone to rolling across a surface when placed on its side. To inhibit or prevent such rolling, a portion or the entirety of the removable cap **19** may have a non-circular cross-section. In the embodiment illustrated in the figures, the removable cap **19** has a distal end with a non-circular cross-section and a proximal end with a circular cross-section. As such, the cross-section of the removable cap **19** gradually transitions from a circular cross-section to a non-circular cross-section when moving from the proximal end of the removable cap **19** to the distal end of the removable cap **19**. In the illustrated embodiment, the non-circular cross-section of the distal end of the removable cap **19** generally takes the form of a square. In other embodiments, the non-circular cross-section may be rectangular, triangular, or any other polygonal or partially polygonal shape, so long one or more sides removable cap **19** are flat or substantially flat to inhibit or prevent rolling. Furthermore, the non-circular cross-section of the distal end of the removable cap **19** may gradually increase in size moving in the distal direction, such that the distal-most portion of the distal end of the removable cap **19** has a larger cross-sectional area than a proximal-most portion of the distal end of the removable cap **19**. This configuration gives the distal end of the removable cap **19** a flared shape, which, in turn, may help a user grip and pull the removable cap **19** off of the housing **12**.

[0167] In some embodiments, the housing **12** and the removable cap **19** may each include a respective anti-rotation feature. These anti-rotation features may engage each other to prevent or inhibit the removable cap **19** from rotating relative to the housing **12** when the removable cap **19** is in a storage position. In some embodiments, the anti-rotation feature of the housing **12** may be adjacent to and generally in-line with the anti-rotation feature of the removable cap **19** when the removable cap **19** is in the storage position. For example, a radial protrusion **9** shown in FIG. **1**A is positioned adjacent to the distal end of the housing **112**. As shown in FIG. **1**B, the removable cap **19** includes an opening **8** may be sized to matingly receive the radial protrusion **9** when the removable cap **19** is in the storage position. As a consequence of this mating engagement, the removable cap **19** may be unable to rotate relative to the housing **12**. This may be beneficial if a user attempts to twist the removable cap **19** when pulling the removable cap **19** off of the housing **12**. In certain cases, rotation of the removable cap **19** may cause a sterile barrier such as an RNS or FNS to rotate, which, in turn, may cause a tip of a needle to core into a seal member within the RNS or FNS. Thus, having the radial protrusion **9** disposed within the opening **8** at least during the initial moments of cap removal may prevent coring of the needle. In alternative embodiments, the opening **8** may be formed in the wall of the housing **12** and the radial protrusion **9** may extend in the proximal direction from a proximal end of the removable cap **19**.

[0168] In other embodiments, the removable cap may be permitted and/or intended to rotate with respect to the housing. For example, the removable cap may include feature(s) that translate rotational movement of the removable cap into an axial assist force that helps urge the cap away from the housing. As a more specific example, the removable cap and/or the housing may have a camming surface, such as a wave-shaped surface, that converts rotational movement of the removable cap with respect to the housing into distal axial movement of the removable cap with respect to the housing. The axial assist force provided by such an arrangement may benefit various users including those having limited dexterity and/or strength due to, for example, an illness.

[0169] FIGS. **19**A-**19**B each show an exemplary force profile during the injection process of an exemplary drug delivery device, where relative displacement between the device housing and the guard member is plotted along the x-axis (in millimeters) and resistance is plotted along the y-axis (Newtons). For example, the displacement(along the x-axis) shows the relative axial displacement along axis A between the guard member **32** and the housing **12**. As discussed above, this relative axial displacement may be understood to refer to translational movement of the housing **12** with respect to the guard member **32** (such as in the case where a user urges the housing in the distal

direction towards the user's injection site while the user's tissue prevents the guard member **32** from moving in the same direction) or it may be understood to refer to translational movement of the guard member **32** with respect to the housing (such as in the case where the housing **12** is held in place and a user pushes on the guard member **32** in the proximal direction). In any event, the x-axis (horizontal) of the graph in FIG. **19** shows relative displacement between the guard member **32** and the housing **12**. The y-axis (vertical) of the graph in FIG. **19** shows the resistance force during the various points of relative displacement between the guard member **32** and the housing **12**. For example, at the point where the guard member **32** and housing **12** have experienced approximately 2 mm of relative displacement, the resistance force experienced by the user is approximately 7.75N for the force profile shown in FIG. **19**A. As an even more specific example, the resistance force may refer to the force experienced by a user due to mechanical interactions between components of the device. For example, when first urging the housing **12** towards the injection site during the pre-injection state shown in FIG. **14**, the resistance force is generally equal to the force required to compress spring **51** as well as the force required to urge the inertial rib **32***k* past the ridge **40***c*. The force profile in FIGS. **19**A-**19**B show several exemplary, potential desired force and displacement values, and thus it is understood that these values may vary depending on the design of the previously-noted interactions.

[0170] Nonetheless, as shown in the exemplary force profile in FIG. **19**A, the initial resistance force is relatively low for the first approximately 1 mm of travel between the guard member **32** and the housing, whereupon at point **202** the resistance force quickly increases (primarily due to the force required to urge the inertial rib **32***k* past the ridge **40***c*) to a peak resistance force at point **204**. Once the inertial rib **32***k* has cleared the ridge **40***c* (FIG. **15**A), the resistance force quickly decreases to point **206**, where the resistance force is primarily due to forces required to compress spring **51** (FIG. **14**), forces required to compress spring **35** (FIG. **11**B), and frictional forces between various moving components within the device. At point **208** the needle is inserted into the user's tissue and at point **210** the injection stage commences and the drug **22** is injected into the user's tissue. Once the user overcomes the peak resistance force at point **204**, the user's inertia may drive the housing and the drug storage container toward the injection site, prompting the needle insertion. This stage of the injection (between point **204** and **208**) may occur over a relatively short period of time, due to the user's inertia, to increase the likelihood that the needle is fully inserted rather than partially inserted and to decrease the likelihood that the user stops movement of the device before or during partial needle insertion. In other words, once the user clears the peak resistance force at point **204**, the user may have “committed” to the needle insertion and/or the injection process.

[0171] FIG. **19**B shows another exemplary force profile, where the peak force (point **304**) is lower than the corresponding point (**204**) in FIG. **19**A so as to require a lower initial force for the user to commit to the insertion. This force profile may make the user less likely to stop the process during the initial depression (point **302**), such as prematurely removing the device from the tissue. However, it may be desirable to have the peak force **304** high enough to reduce the likelihood that the user stops the injection between the peak force **304** and the needle insertion **308**. In other words, the vertical distance(along the y-axis) between points **304** and **308** should be large enough to cause this stage of the injection to occur over a relatively short period of time.

[0172] FIGS. **20**A through **20**G show a distal portion of an alternative design of a device **400**, primarily showing a housing **412**, a guard member **432**, a lock ring **440**, and a lock ring biasing member **451**. As shown in FIG. **20**A and FIG. **22**, the guard member **432** includes an annular base portion **432***a*, a pair of longitudinally-extending arms **432***b*, a ridge **432***h*, a plurality of inner ribs (discussed in more detail below), and at least one opening **432***x* (also referred to as a hole in the annotations to some of the figures) formed through at least one of the ribs and a wall of the guard member. The opening **432***x* need not be an opening formed through the entire wall of the guard member **432**. For example, the opening may be merely a disconnection in the long rib or a

protrusion section with a shorter height rather than a cut-out of the wall of the guard member **432** and a portion of the rib. The inner ribs of the guard member **432** include a first rib that is preferably longer than the other ribs(a.k.a. the long rib **432***r*), and a pair of shorter ribs **432***s*, **432***t*. The opening **432***x* is formed through the long rib **432***r* and is aligned with and sized such as to selectively receive a component of the lock ring **440**, as will be discussed further below. As shown in FIG. **20**A and FIG. **23**, the lock ring **440** includes a plurality of stop surfaces **440***g*, **440***h*, a U-shaped projection **440***w* (configured to be received within the opening **432***x*), and plurality of proximally-facing cam surfaces **440***x*, **440***y*. However, the lock ring **440** shown in FIGS. **20**A and **23** does not have distally-facing cam surfaces corresponding to surface **40***a* in the design shown in FIG. **13**. As shown in FIG. **20**A, during a pre-injection, non-deflection state of the device **400**, each of the two U-shaped projections **440***w* are not initially received within the openings **432***x*. Rather, at this point, the proximal portion of the long rib **432***r* (i.e. the portion of the long rib that is proximal of the opening **432***x*) is received within the U-shaped projection **440***w* such as to prevent the lock ring from moving upwards (proximal direction) with respect to the guard member. As the housing **412** moves downward (distally) and/or the guard member **432** moves upward (proximally), as shown in FIG. **20**B, the lock ring **440** is able to move upward (proximally) from the spring **451**, thereby causing cam surfaces on the housing **412** to contact the lock ring camming surfaces **440***x*, **440***y* and rotationally urge the lock ring. At the stage shown in FIG. **20**B, the lock ring **440** is unable to rotate due to the proximal portion of the long rib **432***r* being aligned with/received within the U-shaped projection **440***w*. Also as shown in FIG. **20**B, the housing cam surface **412***x* engages the lock ring cam surface **440***y*. However, as the relative movement between the guard member and the housing progresses to the state shown in FIG. **20**C, the engagement between the housing cam surface **412***x* and the lock ring cam surface **440***y*, combined with further relative movement between the guard member and the housing cause the following: (1) the engagement between the housing cam surface **412***x* and the lock ring cam surface **440***y* halts upward movement of the lock ring so that the proximal portion of the long rib **432***r* is able to move out of alignment with/engagement with the U-shaped projection **440** such that the U-shaped projection **440***w* is now aligned with the opening **432***x* and (2) the respective cam surface engagement **412***x*, **440***y* causes the lock ring **440** to rotate. As shown in FIG. **20**D, the lock ring rotates to a point (roughly two-thirds of its total rotation) where it is now rotationally constrained by the short ribs **432***s*, **432***t* in the guard member (more specifically, a stop surface **440***v* shown in FIG. **23** engages the short ribs **432***s*, **432***t*). In the state shown in FIG. **20**E, the guard member arms **432***b* sufficiently move relative to the housing **412** such that the injection sequence initiates. As shown in FIG. **20**F, once the user releases pressure on the housing and permits relative proximal movement of the housing and/or distal movement of the guard member, the lock ring is rotationally constrained until stop surface **440***v* clears the short ribs **432***s*, **432***t* and the lock ring rotates into a lock out configuration shown in FIG. **20**G.

[0173] FIGS. **26**A through **26**D show another alternative design of a device **600**, primarily showing a housing **612**, a guard member **632**, a lock ring **640**, and a lock ring biasing member **651**. As shown in **26**C, the guard member **632** includes an annular base portion **632***a*, a pair of longitudinally-extending arms **632***b*, a ridge **632***h*, a plurality of inner ribs (discussed in more detail below), and at least one opening **632***x* (also referred to as a hole herein) formed through at least one of the ribs and a wall of the guard member. Each of the ribs of the guard member **632** may be configured as a radially inwardly extending protrusion. The opening **632***x* need not be an opening formed through the entire wall of the guard member **632**. For example, the opening **632***x* may be merely a disconnection in the long rib or a protrusion section with a shorter height rather than a cut-out of the wall of the guard member **632** and a portion of the rib. The opening **632***x* is formed through rib **632***r* and is aligned with and sized such as to selectively receive a component of the lock ring **640**, as will be discussed further below. As shown in FIGS. **26**A, **26**B, and **26**D, the lock ring **640** includes a plurality of stop surfaces **640***g*, **640***h*, at least one tab-shaped projection **640***w*

(configured to be received within the opening **632***x*), and plurality of proximally-facing camming surfaces **640***y*. As illustrated in FIG. **26**A, each tab-shaped projection **640***w* may be configured as a radially outwardly extending protrusion and may include proximally-facing camming surface **640***z*. As shown in FIG. **26**D, during a pre-injection, partial-deflection state of the device **600**, each of the two tab-shaped projections **640***w* are not initially received within the openings **632***x*. Rather, at this point, a proximally-facing camming surface **612***x* of housing **612** engages the distally-facing camming surface **640***y* of the lock ring **640** to prevent or resist the lock ring **640** from moving upwards (proximal direction) with respect to the guard member **632**. At the same time, the tab-shaped projections **640***w* are each respectively engaged with a pair of ramp surfaces **632***y* (also referred to herein as proximally-facing camming surfaces **632***y*). At this stage of the injection, the guard member **632** has been partially deflected (such as in FIG. **20**B) but the lock ring **640** has not yet rotated and the guard member **632** has not yet moved upwards a distance sufficient to initiate the injection sequence. At this point, the user will feel a resistance to further movement of the injector housing **612**, due to the respective engagements described above, namely the proximally-facing camming surface **612***x* of the housing **612** with the distally-facing camming surface **640***y* of the lock ring **640** and the proximally-facing camming surface **640***z* of the tab-shaped projection **640***w* of the lock ring **640** with the guard member ramp surface **632***y*. This resistance may or likely will prompt the user to press down on the injector with a force sufficient to overcome the resistance (i.e. the peak resistance of the injector). The peak resistance is caused by the aforementioned interactions (the distally-facing camming surface **612***x* of the housing **612** with the proximally-facing camming surface **640***y* of the lock ring **640** and the distally-facing camming surface **640***z* of the tab-shaped projection **640***w* of the lock ring **640** with the guard member ramp surface **632***y*) and it is overcome (i.e. released) when the user's force is sufficient such that the tab-shaped projection **640***w* of the lock ring **640** slides along the guard member ramped surface **632***y* and the proximally-facing camming surface **640***y* of the lock ring **640** will slide along the distally-facing camming surface **612***x* of the housing **612** (to the left in FIG. **26**D). In other words, the lock ring **640** will rotate in the direction of arrow **601** and will travel slightly downward (distally) shown in FIG. **26**D. Once the lock ring **640** rotates enough so that the lock ring tab-shaped projection **640***w* has cleared the guard member ramped surface **632***y*, the guard member **632** will be able to move axially upward (proximally). At this point, two things will happen: (1) the guard member **632** will translate in the proximal direction a sufficient distance such as to initiate the injection sequence and (2) the lock ring tab-shaped projection **640***w* will become axially aligned with guard member opening **632***x* (FIG. **26**C) and thereby allow the lock ring **640** to rotate in the direction of arrow **602** (FIG. **26**D) and slightly upwards (proximal direction) due to the interaction between the proximally-facing camming surface **640***y* of the lock ring **640** and the distally-facing camming surface **612***x* of the housing **612**. After the injection is initiated, the lock ring **640** will be in a position where it can lock-out the shield, similar to the other embodiments described above. The injector **600** may be designed such that events (1) and (2) occur simultaneously, so that once the guard member translates a distance sufficient to initiate the injection, the lock ring will rotate an angle sufficient to initiate the lock-out sequence. This may be desirable to substantially or completely prevent a user from attempting to perform multiple injections. This may also be desirable to substantially or completely prevent the lock-out sequence from initiating without the injection sequence also initiating. In other words, the above configuration may reduce the likelihood that a user has a locked-out injector with an undelivered dose.

[0174] To facilitate rotation of the lock ring **640** relative to the housing **612** and/or the guard member **632**, any two or combination of the following may be parallel to each other: the distally-facing camming surface(s) **612***x* of the housing **612**, the proximally-facing camming surface(s) **632***y* of the guard member **632**, the distally-facing camming surface(s) **640***z* of the lock ring **640**, and the proximally-facing camming surface(s) **640***y* of the lock ring **640**.

[0175] FIGS. **21**A through **21**F show a distal portion of another alternative design of a device **500**,

primarily showing a housing **512**, a guard member **532**, a lock ring **540**, and a lock ring biasing member **551**. The components of the device **500** are similar to those on the device **400**, except that instead of the U-shaped projection **440***w*, the lock ring **540** has only a pair of parallel projections **540***w* that do not have a horizontal projection connecting them. In other words, the projections **540***w* have the "side portions" of a U-shape but do not have the "bottom portion" of a U-shape. In the state shown in FIG. **21**A, the projections **540***w* are received within a long rib of the guard member **532** to prevent rotational movement of the lock ring. As relative movement occurs between the guard member and the housing, as shown in FIG. **21**B, the projections **540***w* become aligned with an opening in the guard member, thereby allowing rotational movement of the lock ring with respect to the guard member(and urged by a camming surface on the housing). As shown in the state in FIG. **21**C, the lock ring then rotates until stop surface **440***v* engages the short ribs in the guard member. FIG. **21**D shows the distal components of the device during the injection activation. FIG. **21**E shows the state of the distal components once the user has released pressure and the guard member is able to move (extend distally) relative to the housing. FIG. **21**F shows the lock-out configuration.

[0176] FIG. **24** provides a graph for comparing the force profiles illustrated in FIGS. **19**A and **19**B with force profiles attributable to the drug delivery device **400** shown in FIGS. **20**A-**20**G and the drug delivery device **500** shown in FIGS. **21**A-**21**F. Similar to FIGS. **19**A and **19**B, FIG. **24** plots the resistance force experienced by a user versus displacement of a shield (e.g., the shield guard **32**). Additionally, FIG. **24** identifies where in each force profile a lock point associated with a lock ring is designed to occur. FIG. **24** shows that the lock point for the force profiles in FIGS. **19**A and **19**B occurs at the same shield displacement as when the user experiences a peak resistance. By contrast, the lock point for the force profiles associated with drug delivery devices **400** and **500** does not coincide with a shield displacement corresponding to a peak resistance experienced by the user.

[0177] Continuing with FIG. **24**, the force profile associated with the drug delivery device **400** is similar to the force profiles in FIGS. **19**A and **19**B in that prior to needle insertion the user experiences a sudden jump in resistance caused by displacing the shield. Unlike the force profiles in FIGS. **19**A and **19**B, the resistance experienced by the user of the drug delivery device **400** may continue to increase after this jump (until the activation point). FIG. **24** shows that the user of the drug delivery device **500** may not experience a sudden jump in resistance during shield displacement but rather may experience a gradual increase in resistance until the activation point. A manufacturer may choose one of the force profiles illustrated in FIG. **24** or a different force profiles depending on, for example, a desired user experience, physical and/or mental abilities of a target user or patient population, mechanical safety considerations, and/or additional considerations.

[0178] From the foregoing, it can be seen that the present disclosure advantageously provides a streamlined design for a drug delivery device having automated features. Various mechanisms and components of the drug delivery device may interact with each other in synergistic ways so as to limit the number of moving parts required by the drug delivery device, thereby improving the reliability of the drug delivery device and saving costs, as well as providing other benefits and advantages.

[0179] As will be recognized, the devices and methods according to the present disclosure may have one or more advantages relative to conventional technology, any one or more of which may be present in a particular embodiment in accordance with the features of the present disclosure included in that embodiment. Other advantages not specifically listed herein may also be recognized as well.

[0180] 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.

[0181] 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.

[0182] 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 filgastrim, pegylated G-CSF, pegylated hu-Met-G-CSF) and Neupogen® (filgrastim, G-CSF, hu-MetG-CSF), UDENYCA® (pegfilgrastim-cbqv), Ziextenzo® (LA-EP2006; pegfilgrastim-bmez), or FULPHILA (pegfilgrastim-bmez).

[0183] 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® (methyoxy 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.

[0184] 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-α4β7 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™ (lymphostat 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-TNFα 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. Pat. No. 7,153,507); Tysabri® (natalizumab, anti-α4integrin mAb); Valortim® (MDX-1303, anti-β. 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| receptor and receptor accessory protein); VEGF trap (Ig domains of VEGFR1 fused to IgG1 Fc); Zenapax® (daclizumab); Zenapax® (daclizumab, anti-IL-2Ra mAb); Zevalin® (ibritumomab tiuxetan); Zetia® (ezetimibe); Orencia® (atacicept, TACI-Ig); anti-CD80 monoclonal antibody (galiximab); anti-CD23 mAb (lumiliximab); BR2-Fc (huBR3/huFc fusion protein, soluble BAFF antagonist); CNTO 148 (golimumab, anti-TNFα mAb); HGS-ETR1 (mapatumumab; human anti-TRAIL Receptor-1 mAb); HuMax-CD20 (ocrelizumab, anti-CD20 human mAb); HuMax-EGFR (zalutumumab); M200 (volociximab, anti-α531 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-IFNα 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/hCGβ mAb (MDX-1307); anti-mesothelin dsFv-PE38 conjugate (CAT-5001); anti-PD1mAb (MDX-1106 (ONO-4538)); anti-PDGFRa antibody (IMC-3G3); anti-TGFβ mAb (GC-1008); anti-TRAIL Receptor-**2** human mAb (HGS-ETR2); anti-TWEAK mAb; anti-VEGFR/FIt-1 mAb; and anti-ZP3 mAb (HuMax-ZP3).

[0185] 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, vidupiprant or panitumumab. In some embodiments, the reservoir of the drug delivery device may be filled with or the device can be used with IMLYGIC® (talimogene laherparepvec) or another oncolytic HSV for the treatment of melanoma or other cancers including but are not limited to OncoVEXGALV/CD; OrienX010; G207, 1716; NV1020; NV12023; NV1034; and NV1042. In some embodiments, the drug delivery device may contain or be used with endogenous tissue inhibitors of metalloproteinases (TIMPs) such as but not limited to TIMP-3. In some embodiments, the drug delivery device may contain or be used with Aimovig® (erenumab-aooe), anti-human CGRP-R (calcitonin gene-related peptide type 1 receptor) or another product containing erenumab for the treatment of migraine headaches. Antagonistic antibodies for human calcitonin gene-related peptide (CGRP) receptor such as but not limited to erenumab and bispecific antibody molecules that target the CGRP receptor and other headache targets may also be delivered with a drug delivery device of the present disclosure. Additionally, bispecific T cell engager (BiTE®) antibodies such as but not limited to BLINCYTO® (blinatumomab) can be used in or with the drug delivery device of the present disclosure. In some embodiments, the drug delivery device may

contain or be used with an APJ large molecule agonist such as but not limited to apelin or analogues thereof. In some embodiments, a therapeutically effective amount of an anti-thymic stromal lymphopoietin (TSLP) or TSLP receptor antibody is used in or with the drug delivery device of the present disclosure. In some embodiments, the drug delivery device may contain or be used with Avsola™ (infliximab-axxq), anti-TNF a 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-isoindol-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 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 p 40 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 (BiTER). In some embodiments, the drug delivery device may contain or be used with AMG 256 or another product containing an anti-PD-1×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×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×CD3 BITER (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×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×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×CD3 BITE® (bispecific T cell engager) construct.

[0186] 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.

[0187] 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).

Claims

1.-**20**. (canceled)
21. A drug delivery device comprising: a housing defining a longitudinal axis and having an opening; 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 toward a distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, the plunger including a body portion having an inner wall defining an axial chamber and an outer wall cooperating with the inner wall to define a body thickness less than 2 millimeters; and a plunger biasing member disposed at least partially within the axial chamber, the plunger biasing member being configured to urge the plunger toward the distal end of the drug storage container.
22. The drug delivery device of claim 21, wherein the body thickness is less than 1 millimeter.
23. The drug delivery device of claim 21, wherein the body thickness is less than 0.6 millimeters.
24. The drug delivery device of claim 21, wherein the body thickness is less than 0.4 millimeters.
25. The drug delivery device of claim 21, wherein the body thickness is less than 0.3 millimeters.
26. The drug delivery device of claim 21, wherein the body thickness is less than 0.2 millimeters.
27. The drug delivery device of claim 21, wherein the body thickness is less than 0.1 millimeters.
28. The drug delivery device of claim 21, wherein the body thickness is less than 0.05 millimeters.
29. The drug delivery device of claim 21, wherein the body portion has a hollow tubular shape.
30. The drug delivery device of claim 21, wherein the body portion is made of metal.
31. The drug delivery device of claim 21, wherein the body portion is made of a non-metal.
32. A drug delivery device comprising: a housing defining a longitudinal axis and having an opening; 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 toward a distal end of the drug storage container to expel a drug from the drug storage container through the delivery member, the plunger including an annular wall having an inner surface defining an interior space and an outer surface cooperating with the inner surface to define a thickness of the annular wall of less than 2 millimeters; and a plunger biasing member disposed at least partially within the interior space of the plunger, the plunger biasing member being configured to urge the plunger toward the distal end of the drug storage container.
33. The drug delivery device of claim 32, wherein the thickness of the annular wall of the plunger is less than 1 millimeter.
34. The drug delivery device of claim 32, wherein the thickness of the annular wall of the plunger is less than 0.6 millimeters.
35. The drug delivery device of claim 32, wherein the thickness of the annular wall of the plunger is less than 0.4 millimeters.
36. The drug delivery device of claim 32, wherein the thickness of the annular wall of the plunger is less than 0.3 millimeters.
37. The drug delivery device of claim 32, wherein the thickness of the annular wall of the plunger is less than 0.2 millimeters.
38. The drug delivery device of claim 32, wherein the thickness of the annular wall of the plunger is less than 0.1 millimeters.
39. The drug delivery device of claim 32, wherein the annular wall of the plunger is made of metal.

40. The drug delivery device of claim 32, wherein the annular wall of the plunger is made of non-metal.