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SUPPORTING PATIENT USE OF A DRUG  
DELIVERY DEVICE****Publication Classification**(51) **Int. Cl.****G06F 19/00** (2006.01)**A61M 5/32** (2006.01)**A61M 5/20** (2006.01)**A61M 5/315** (2006.01)**G06Q 50/00** (2006.01)**A61M 5/142** (2006.01)(52) **U.S. Cl.****CPC** ..... **G06F 19/3468** (2013.01); **G06F 19/325**(2013.01); **G06Q 50/01** (2013.01); **G06F****19/3418** (2013.01); **A61M 5/14248** (2013.01);**A61M 5/20** (2013.01); **A61M 5/31568**(2013.01); **A61M 5/31501** (2013.01); **A61M****5/3243** (2013.01); **A61M 5/326** (2013.01);**A61M 2005/3267** (2013.01); **A61M 2205/3368**(2013.01); **A61M 2205/6009** (2013.01); **A61M****2205/50** (2013.01); **A61M 2205/3553**(2013.01); **A61M 2205/502** (2013.01); **A61M****2205/52** (2013.01); **A61M 2205/581** (2013.01)(71) Applicant: **AMGEN INC.**, Thousand Oaks, CA  
(US)(72) Inventors: **Adam B. McCullough**, Westlake  
Village, CA (US); **Ferry Tamtoro**, San  
Ramon, CA (US); **Huaying Yang**,  
Vernon Hills, IL (US); **Mark Ka Lai**  
**Lee**, Newbury Park, CA (US); **Desheng**  
**Yin**, Thousand Oaks, CA (US); **Scott**  
**R. Gibson**, Granada Hills, CA (US);  
**Donald Busby**, Thousand Oaks, CA  
(US); **Peter V. Shultz**, Woodland Hills,  
CA (US); **Keith P. Kogler**, Simi Valley,  
CA (US); **Basel Hasan Taha**, Westlake  
Village, CA (US); **Jimmie L. Ward**,  
Golden, CO (US); **Steven William**  
**Badelt**, Los Angeles, CA (US)(21) Appl. No.: **15/315,954**(22) PCT Filed: **Jun. 3, 2015**(86) PCT No.: **PCT/US15/33946**

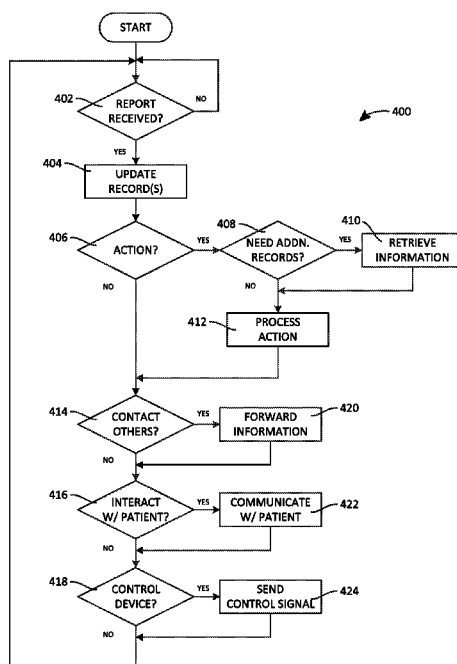
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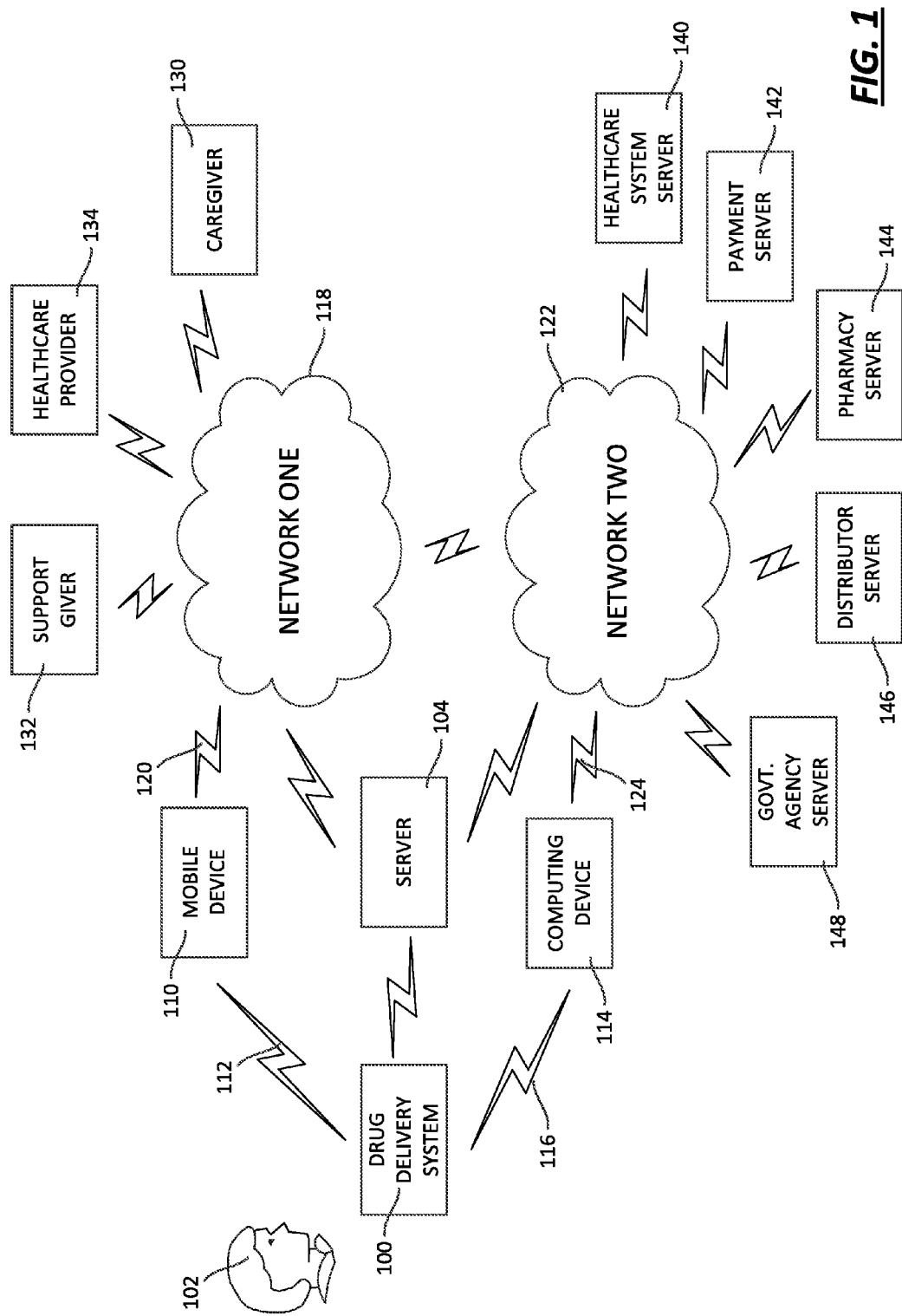
(2) Date: **Dec. 2, 2016****Related U.S. Application Data**(60) Provisional application No. 62/007,007, filed on Jun.  
3, 2014.

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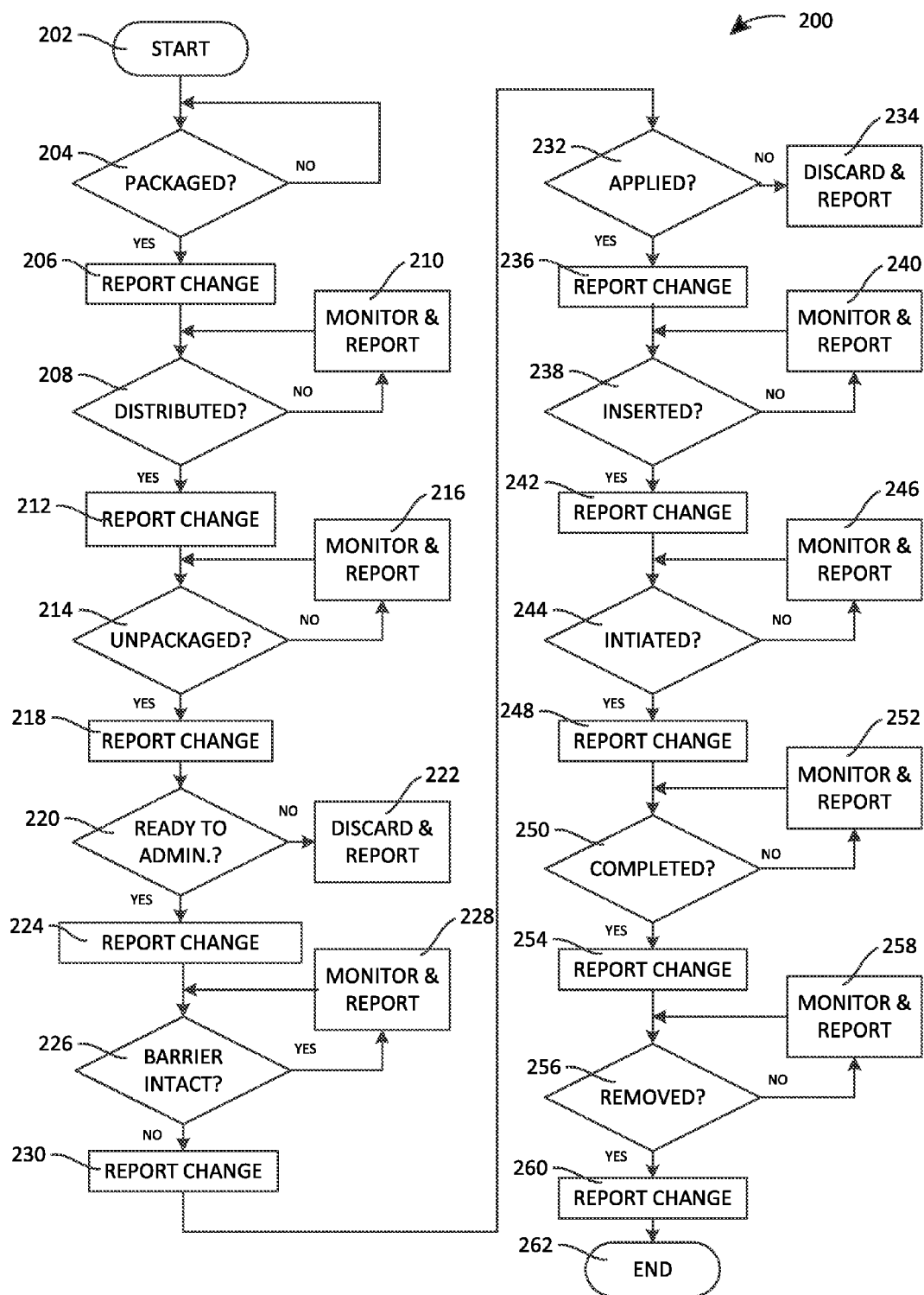
**ABSTRACT**

Systems and methods are disclosed herein for supporting a patient's use of a drug delivery device. The patient may be associated with a support group via, for example, a social networking service for the purpose of increasing the likelihood that the patient will comply with a treatment regimen. Based on data representative of a condition and/or operational state of the drug delivery device, it may be determined whether the patient is compliant with the treatment regimen. If the patient is not compliant, the systems and method disclosed herein may transmit a communication to the support group requesting the support group to counsel the patient about the treatment regimen. The counseling may take the form of words of encouragement, coaching, suggestions, reminders, and/or any other communication likely to urge the patient to comply with the treatment regimen.

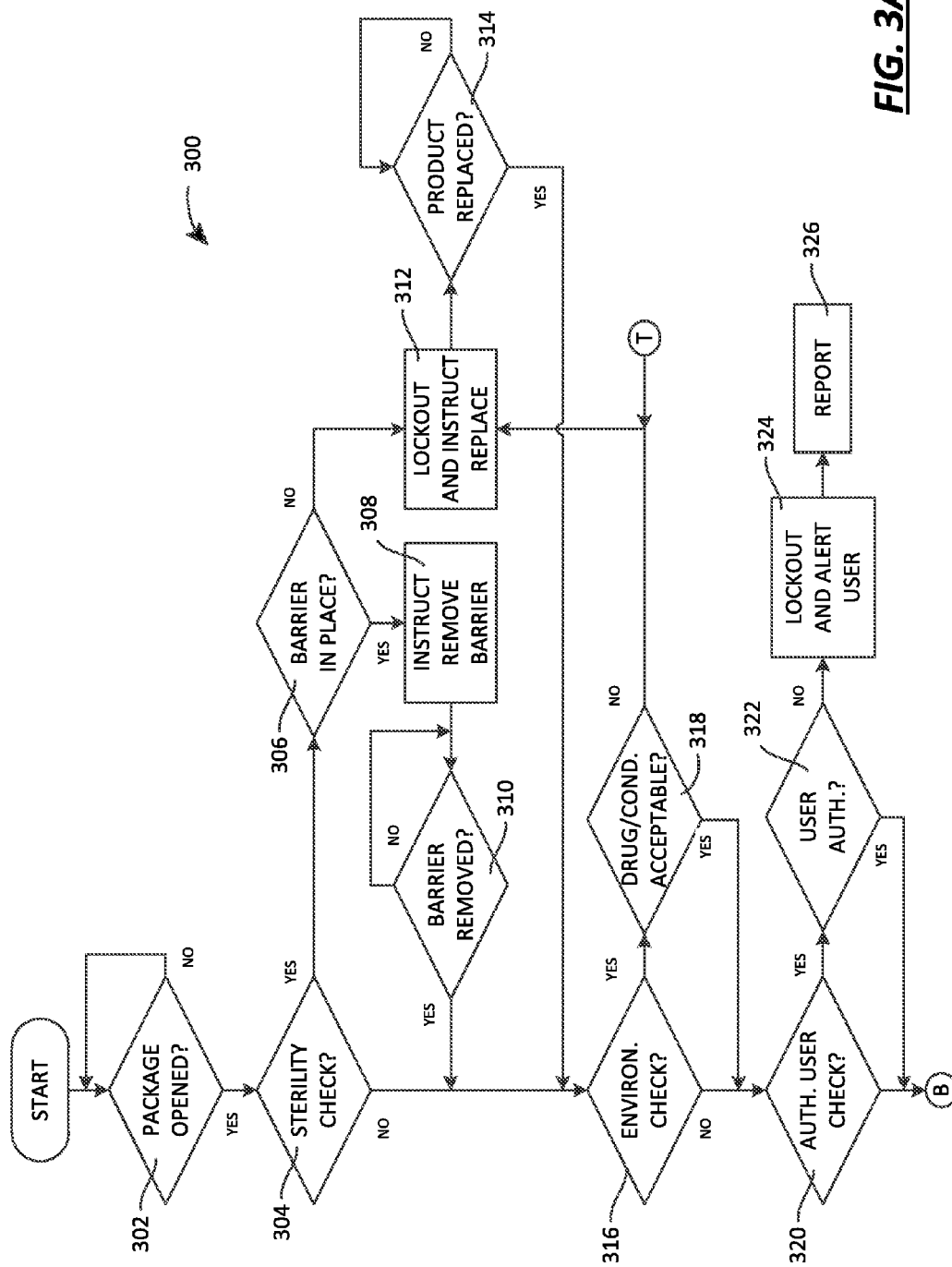


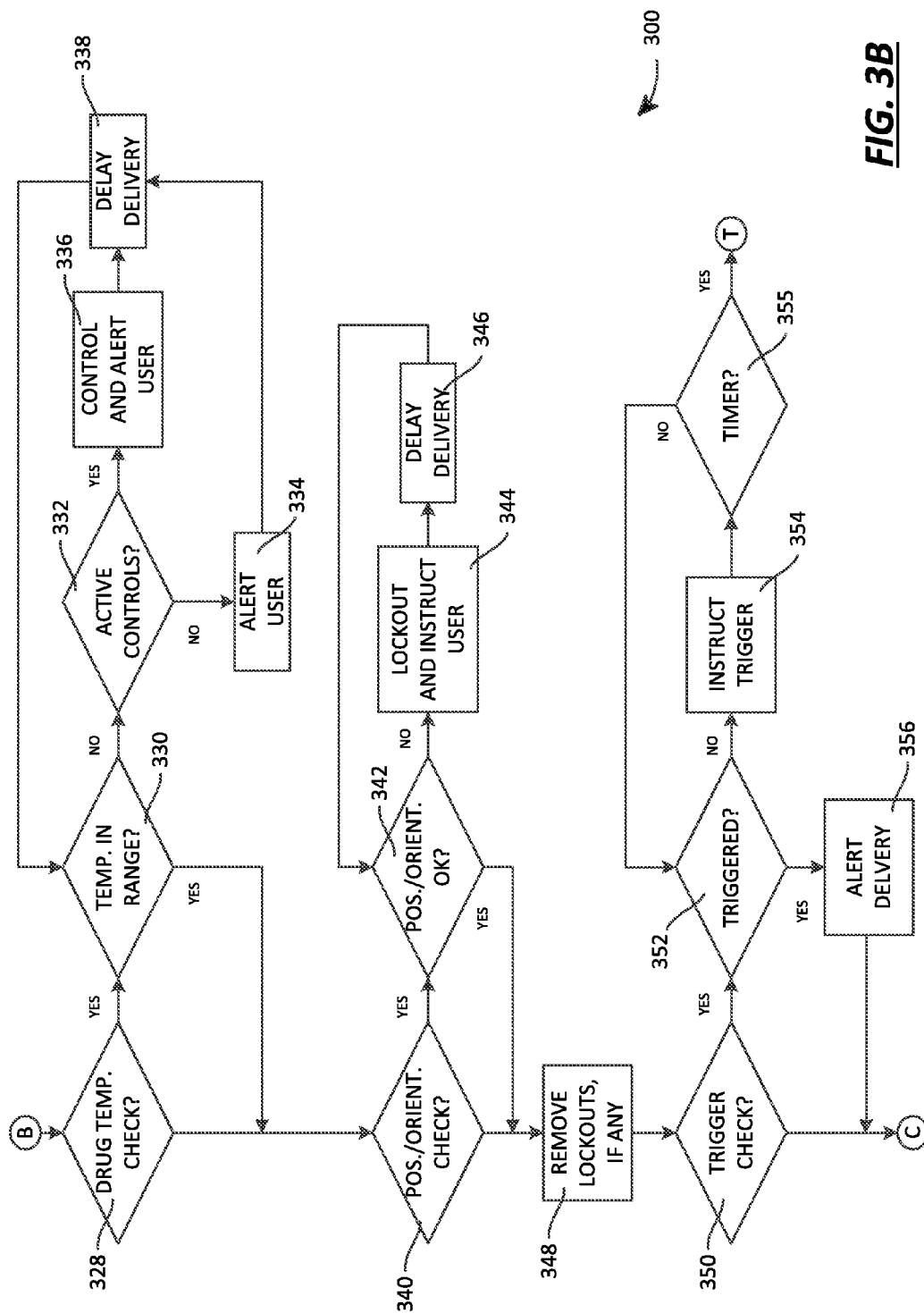


**FIG. 1**

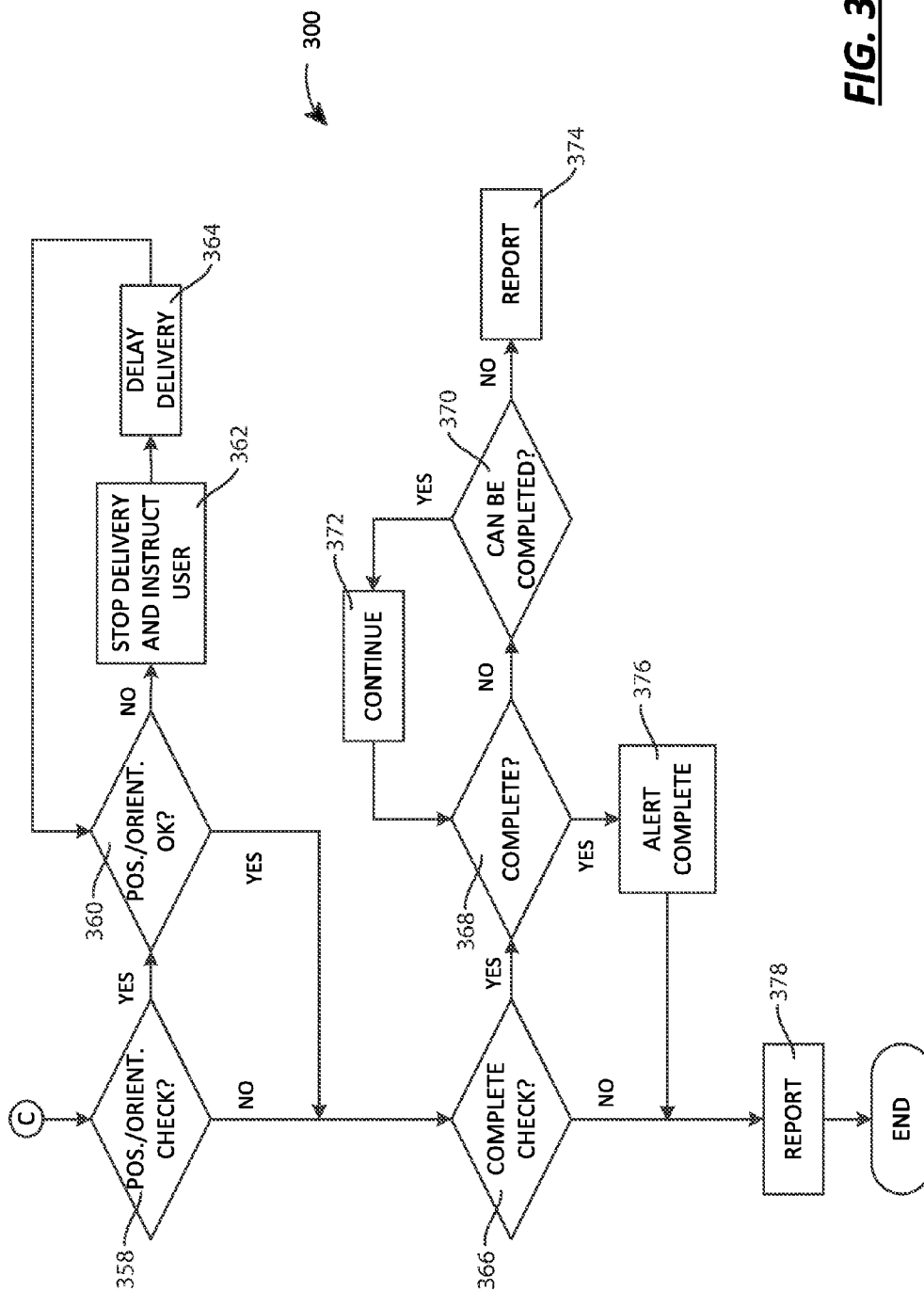


**FIG. 2**

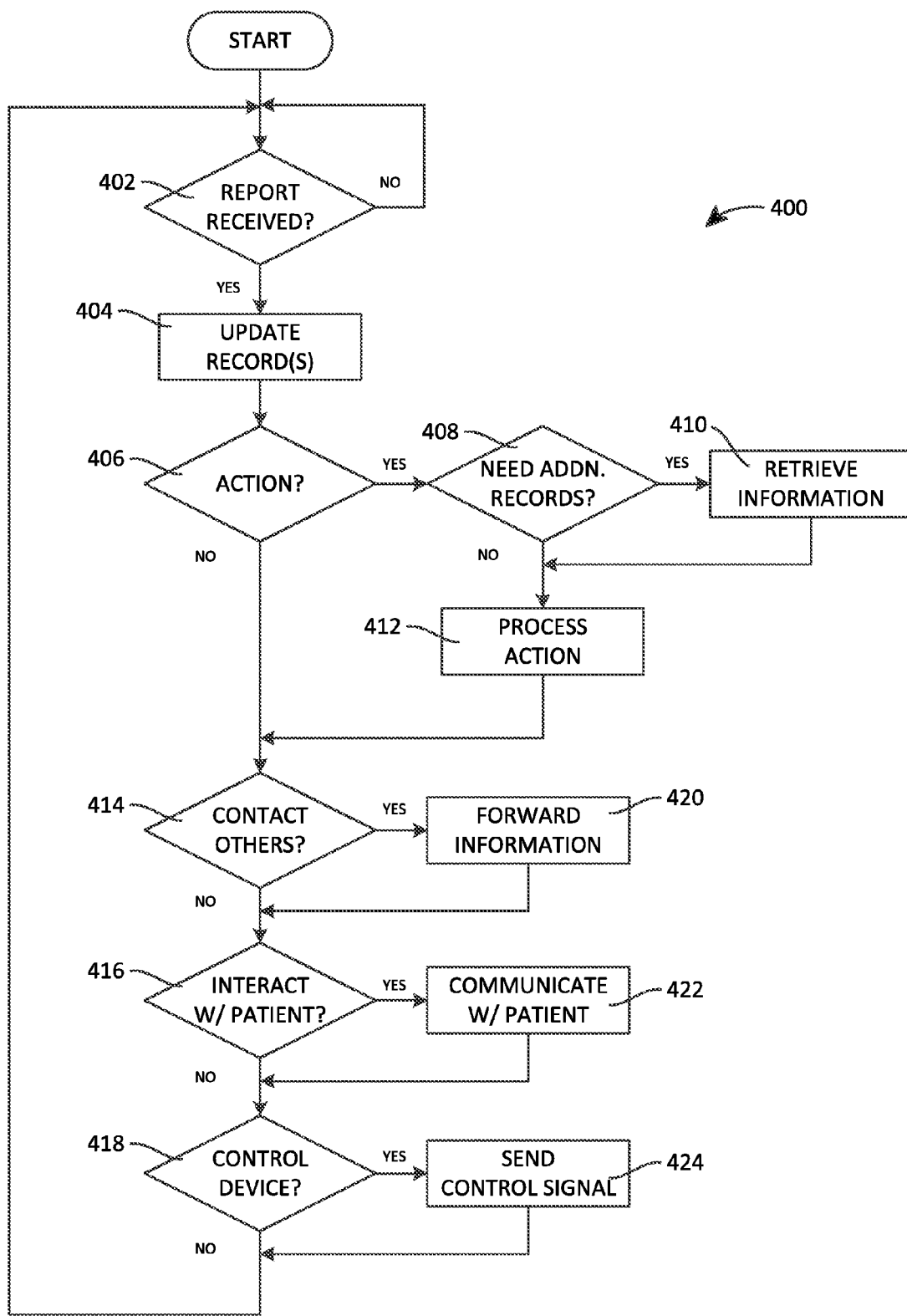




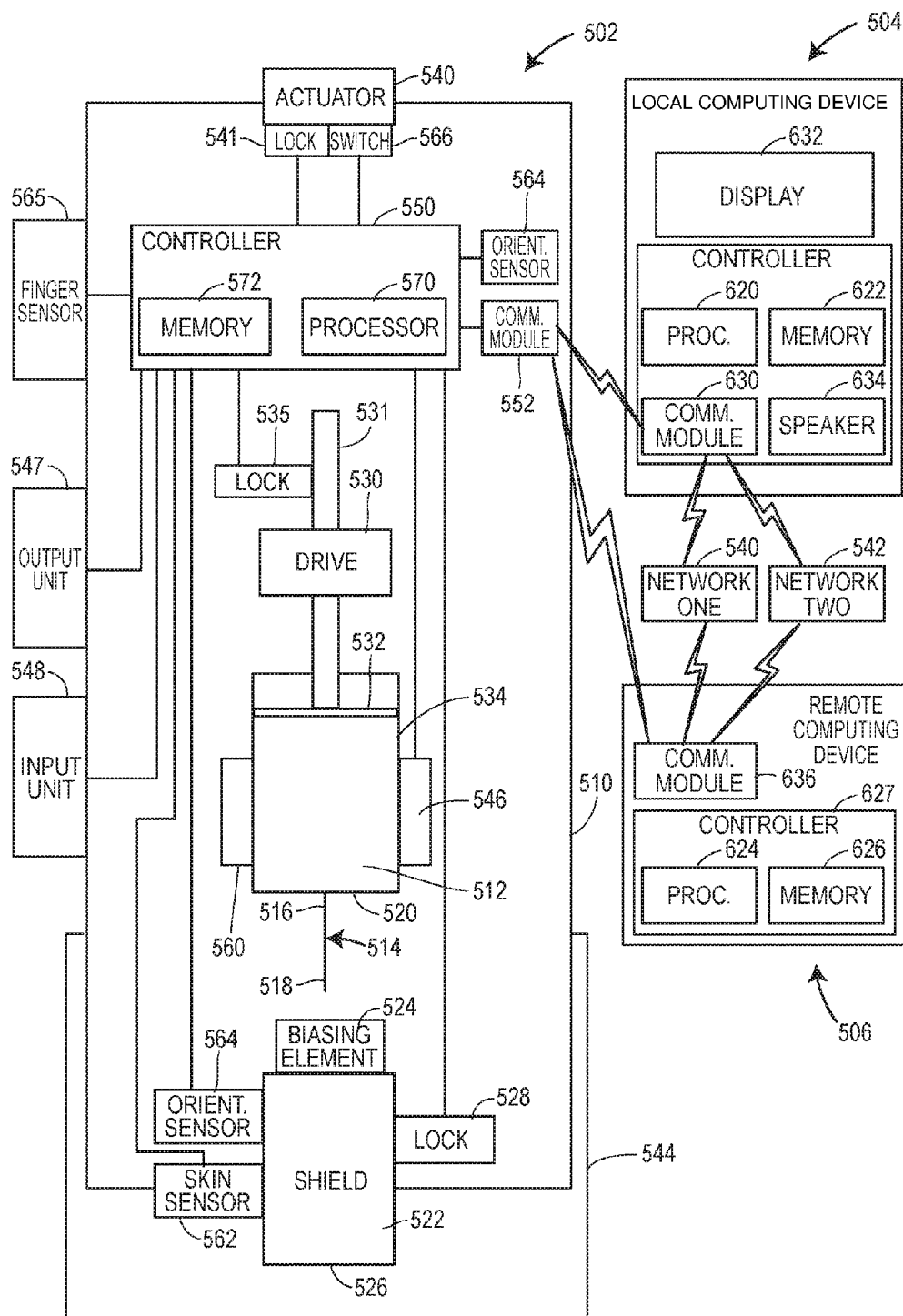
**FIG. 3B**



**FIG. 3C**

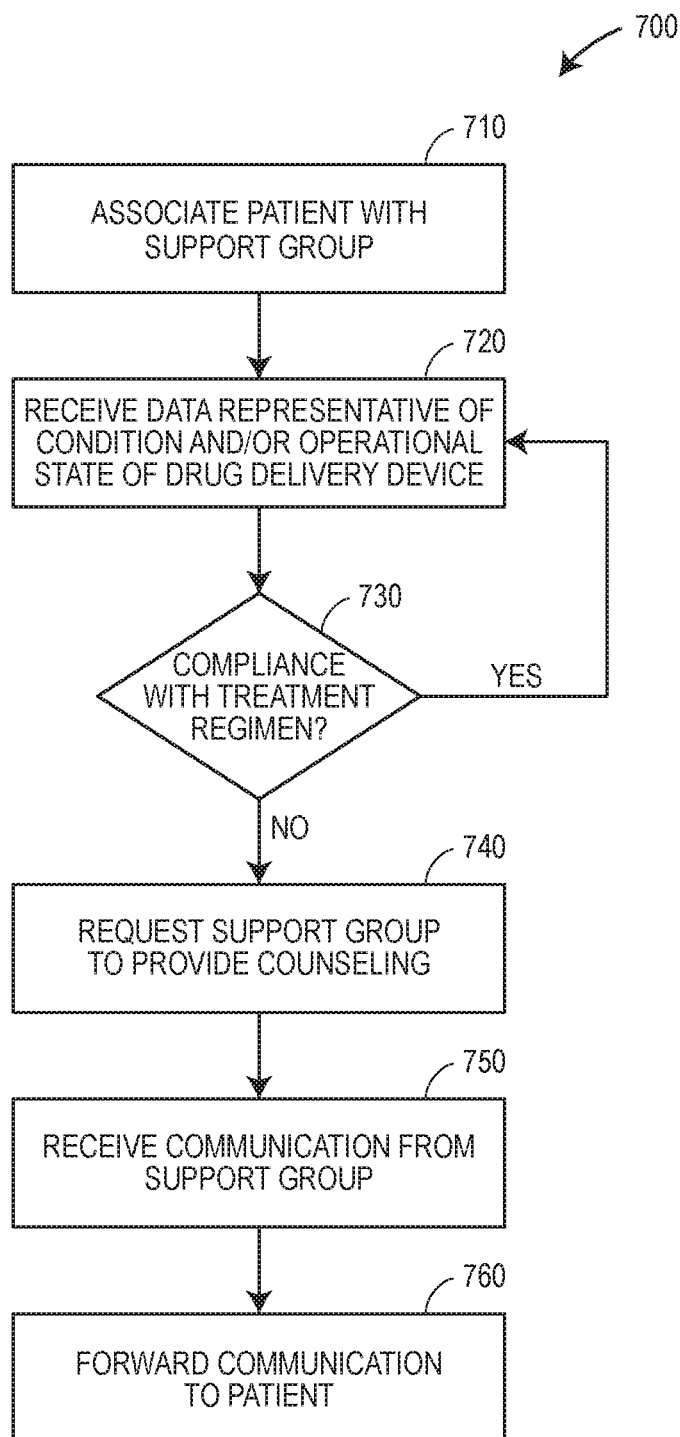


**FIG. 4**



**FIG. 5**



**FIG. 6**

## SYSTEMS AND METHODS FOR SUPPORTING PATIENT USE OF A DRUG DELIVERY DEVICE

### CROSS-REFERENCE TO RELATED APPLICATION

[0001] The priority benefit of U.S. Provisional Patent Application No. 62/007,007, filed Jun. 3, 2014, is claimed, and the entire contents thereof are expressly incorporated herein by reference.

### BACKGROUND

[0002] The present disclosure generally concerns systems and methods for encouraging a patient to use a drug delivery device in accordance with a treatment regimen.

[0003] Drugs can be administered through the use of drug delivery devices, such as autoinjectors or on-body injectors or infusers. These devices may replace older delivery systems using the combination of a syringe and a vial containing the drug or medicament, or a pre-filled syringe. Auto-injectors and on-body injectors may be used to automate the injection and delivery or administration process, thereby simplifying the process for certain patient groups or sub-groups for which use of the syringe/vial combination or pre-filled syringe systems is disadvantageous, whether because of physiological or psychological impediments.

[0004] Despite the automation provided by drug delivery devices, patients may experience challenges in being adherent or compliant with a treatment regimen. For example, certain patients may not perform the injections according to the treatment regimen, having forgotten to perform the injection at all. Other patients may perform the injections, but then be unable to remember whether they performed the injections because they become distracted before they are able to record that they did so. Some patients may elect not to perform the injections because of misunderstandings or miscommunications of when or how the medication will affect the patient's disease or symptoms, especially where the effects are not felt by the patient until a considerable portion of the treatment regimen has been performed.

[0005] Some patients may be more likely to follow a treatment regimen if they are provided with support and/or encouragement from others (e.g., a healthcare provider, a caregiver, a family member, a friend, another individual with a similar medical condition, etc.). However, the people who would potentially be willingly to provide such support and/or encouragement may be unaware that the patient has failed to follow the treatment regimen.

[0006] To address one or more of the challenges or needs mentioned above, the present disclosure sets forth various systems and methods to support patient use of a drug delivery device and facilitate compliance with a treatment regimen.

### SUMMARY

[0007] According to an aspect of the disclosure, provided is a social networking based method of providing a patient with support. The method may include associating the patient with at least one support group. The method may also include receiving data representative of at least one of a condition or an operational state of a drug delivery device associated with the patient. The method may further include determining if the patient is compliant with a treatment

regimen based on the condition or the operational state of the drug delivery device. Furthermore, in response to a determination that the patient is not compliant with the treatment regimen, the method may include transmitting a communication to the at least one support group requesting the at least one support group to counsel the patient about the treatment regimen.

[0008] According to another aspect of the disclosure, a support system for a patient includes a drug delivery system and an external computing device. The drug delivery system may include a reservoir, a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within the patient, one or more sensors, and a first communication module configured to transmit a report representative of at least one of a condition or an operational state of the drug delivery device. The external computing device may include a second communication module configured to receive the report, a processor, and a memory coupled to the processor and configured to store non-transitory, computer-executable instructions. When executed by the processor, the non-transitory, computer-executable instructions may cause the processor to: (i) associate the patient with the at least one support group; (ii) store, in the memory, a predefined criteria for determining compliance with a treatment regimen; (iii) compare the report with the predefined criteria to determine if the patient is compliant with the treatment regimen; and (iv) in response to a determination that the patient is not compliant with the treatment regimen, control the second communication module to transmit a communication to the at least one support group requesting the at least one support group to counsel the patient about the treatment regimen.

[0009] According to a further aspect of the disclosure, provided is a non-transitory, computer-readable storage medium having computer-executable instructions that, when executed at one or more processors of a support system for a patient, cause the one or more processors to: (i) associate the patient with at least one support group; (ii) receive data representative of at least one of a condition or an operational state of a drug delivery device associated with the patient; (iii) determine if the patient is compliant with a treatment regimen based on the condition or the operational state of the drug delivery device; and (iv) in response to a determination that the patient is not compliant with the treatment regimen, transmit a communication to the at least one support group requesting the at least one support group to counsel the patient about the treatment regimen.

### BRIEF DESCRIPTION OF THE DRAWINGS

[0010] FIG. 1 is a schematic diagram of a drug delivery system according an embodiment of the disclosure in communication with one or more computing devices and one or more networks;

[0011] FIG. 2 is a block diagram of a method of operating the drug delivery system illustrated in FIG. 1 according to an embodiment of the disclosure;

[0012] FIGS. 3A-3C is a block diagram of a method of operating the drug delivery system illustrated in FIG. 1 according to another embodiment of the disclosure;

[0013] FIG. 4 is a block diagram of a method of operating a computing device such as is illustrated in FIG. 1 according to an embodiment of the disclosure, the computing device in

communication with a drug delivery system operating according to one of the methods disclosed herein, for example;

**[0014]** FIG. 5 is a schematic illustration of an embodiment of a system including a drug delivery device, a local computing device, and a remote computing device interconnected with communication links and networks; and

**[0015]** FIG. 6 is a flow diagram of an embodiment of a method for supporting a patient's use of a drug delivery device.

#### DETAILED DESCRIPTION

**[0016]** In general, the present disclosure is directed to methods and systems for providing a patient under medical care with a social support network. More particularly, the present disclosure relates to monitoring patient use of a drug delivery device with sensors or other means and linking the patient to a support group who can encourage the patient to comply with a treatment regimen (e.g., a therapeutic regimen). The systems and methods described herein may leverage the capabilities of social networking services (e.g., Facebook, Twitter, etc.) to identify a support group from which the patient is likely to take advice. The presently disclosed methods and systems therefore may increase the likelihood of patient use of the drug delivery device in accordance with a treatment regimen.

**[0017]** The systems and methods may involve the determination of one or more states, which states may be determined through the use of one or more sensors in combination with one or more controllers. The sensors may rely on mechanical, electrical or chemical sensing mechanisms, and the controllers may be mechanical, electrical or electro-mechanical. By way of example and not by way of limitation, the states may relate to the operation of the drug delivery device, or to the condition of the drug delivery device. The system and methods may use the state determination to control the operation of the drug delivery device, and/or may communicate the state determination to other devices, such as third-party servers that may collect, process and/or further disseminate the state determinations received from the system including the drug delivery device, the one or more sensors, and the one or more controllers. In addition or in the alternative, the systems and methods may communicate the state determination to local computing devices, such as a mobile computing device (e.g., cell phone).

**[0018]** A drug delivery system according to the disclosure may include a drug delivery device having a reservoir (which may also be referred to as a primary container, e.g., a syringe, vial or cartridge). The reservoir may contain a drug, which may also be referred to as a medication or a medicament. 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 (e.g., no differentiation is intended between a solution, a gel, or a lyophilized product for example). The drug delivery device also includes delivery cannula having a first end connected to or connectable in fluid communication with the reservoir and a second end to be inserted within a patient. As used herein, the term "delivery cannula" or "cannula" is hereby defined to mean a tube that can be inserted into the body for the delivery of fluid. A cannula may include a rigid or semi-rigid needle or blunt cannula, or may be in a flexible form, by example and not by way of limitation. The cannula may be integrated with

the other elements of the drug delivery device, or the cannula may be separate from the other elements of the drug delivery until immediately prior to use. According to certain embodiments, the drug delivery device may further include an inserter to introduce the second end into the patient, although this is not required according to each embodiment of the disclosure. The inserter may or may not be withdrawn back into the device, thereby leaving the cannula in a patient.

**[0019]** Considering the foregoing description of the drug delivery device, the device may be characterized as an autoinjector or an on-body injector or infuser (the reference to injector intended to include also a reference to an infuser, to the extent that a difference is suggested). Autoinjectors may be single-use devices, administering a single dose during a single application of the device to the user's skin, although autoinjectors are not limited to only single-use devices—they may be multi-use devices as well. On-body injectors may be multi-use devices, administering multiple doses during one or more applications of the device to the user's skin, although on-body devices may also be used as single-use devices. Either autoinjectors or on-body injectors may have assemblies or sub-assemblies that are reusable, in that the assemblies may be used and re-used by refilling the reservoir, by removing an empty reservoir and replacing it with a filled reservoir, or by replacing the cannula, for example.

**[0020]** As noted above, the system or method according to the disclosure will determine one or more states relative to the drug delivery device.

**[0021]** For example, the system or method may determine if the drug delivery device is in one or more operational states (i.e., a state relating to the operation of the drug delivery device to deliver the drug to the patient). A non-exhaustive list of the general operational states may include (i) packaged/ready for distribution; (ii) packaged/distributed; (iii) unpackaged/ready for administration; (iv) sterile barrier removed; (v) device applied; (vi) cannula injected (or inserted); (vii) drug delivery initiated; (viii) drug delivery completed; and (ix) device removed. The system or method may determine specific operational states within each of the general operational states; for example, the system or method may determine if plunger has been moved from a first end of a bore (defining a drug reservoir) to a second end of the bore to determine if the drug delivery device is in the "drug delivery complete" state.

**[0022]** Furthermore, the system or method may determine if the drug delivery device is in one or more condition states (i.e., a state relating to the condition of the drug delivery device, not necessarily related to the operation of the drug delivery device to deliver the drug to the patient). A non-exhaustive list of condition states may include (i) age (e.g., taken with respect to a manufacturing date or an expiration date); (ii) sterility/contamination; (iii) temperature; (iv) temperature history; and (iv) orientation. The determination of a condition state may be considered as part of the determination of an operational state; for example, the determination of the temperature state may be considered as part of the determination of the "ready for administration" state. Alternatively, the operational and condition states may be determined separately.

**[0023]** These states may be determined through the use of one or more sensors. The sensors may be particular to a condition state to be determined: for example, a thermocouple disposed adjacent to the reservoir may be used to

determine the temperature state of the drug delivery device. The sensors may be particular to an operational state to be determined: for example, a switch may be coupled to a needle guard to determine when a needle cap has been removed to determine the “sterile barrier removed” operational state, the switch being open when the needle cap is disposed over the second end of the cannula and the switch being closed when the needle guard is not disposed over the second end of the cannula. Sensors may be used to determine both a condition state and an operational state: for example, the thermocouple may be used to determine the temperature condition state of the device (or more particularly, the drug), and/or the thermocouple may be used to determine the “ready for administration” operational state.

**[0024]** The system or method may use the determined states to control the operation of the drug delivery device. For example, the system may include a controller that is coupled to the sensor and may be coupled to one or more of the assemblies or subassemblies of the drug delivery device described above, or to one or more additional assemblies or subassemblies of the drug delivery device. The controller may be adapted structurally or programmed (if electrical or electro-mechanical) to activate or to inhibit these assemblies or subassemblies in accordance with the determined states. For example, the drug delivery device may include a lockout that limits or completely inhibits the operation of the injector, and the controller may activate the lockout in a reversible fashion if the temperature state of the drug delivery device (and in particular, the drug in the reservoir) is below a threshold state.

**[0025]** The system or method may communicate the determined state(s) to another device or system, which communication may be performed in conjunction with use of the determined state(s) to control the operation of the drug delivery device. For example the system or method may communicate the determined state(s) with a networked device using a communication link. In this sense, a networked device is intended to include any device that communicates with at least one other device over a communication link, and might include communication with a device such as mobile device (e.g., cell phone or mobile computing device) using a Bluetooth connection or a computing device using a Wi-Fi connection, for example. The networked device may communicate the determined states to other computing devices remote from the drug delivery system over the network that includes the networked device such as a server. According to certain embodiments of the present disclosure, the system communicates directly with the network (i.e., without an intermediate networked device—the system would be a networked device) or directly with a remote computing device such as a server (using, for example, a 3G antenna). The state information communicated over network, may then be used, for example, to determine if a patient is in compliance, or if a class of drug delivery devices is exhibiting a systemic malfunction. The state information may be used in other manners as well.

**[0026]** The systems and methods may also include control of the drug delivery device according to information relating to the identity of the drug, the drug delivery device, or the user, and/or communication of this identity information. Identity information relating to the drug may include a drug name, a drug concentration, dose information, a lot number or serial number, and a date of manufacture and/or expiration. Identity information relating to the drug delivery

device may include a device type (e.g., autoinjector, on-body injector), a lot number or serial number, and a date of manufacture. Identity information relating to the user may include a patient name, demographic information, and patient subgroup information. This information may be referred to as “static” information, in contrast to the state information discussed above.

**[0027]** As to the communication of the information, and in particular relative to the identity information discussed immediately above, it will be recognized that not all information may be useful, desired, or even accessible to every different party whether for convenience, patient privacy or data security concerns.

**[0028]** FIG. 1 illustrates a drug delivery system 100 according to an embodiment of the disclosure. The drug delivery system 100 may be associated with a patient 102, who may use the drug delivery system 100, to inject a drug as part of a treatment regimen (e.g., a therapeutic regimen). The drug delivery system 100 includes, but is not limited to, the drug delivery device describe below in more detail. The drug delivery system 100 may communicate with a computing device 104 (e.g., a server) via one or more intermediate computing devices and/or one or more networks. In turn, the server 104 may communicate with the drug delivery system 100, the patient 102, and one or more computing devices (with their associated parties) via one or more intermediate computing devices and/or one or more networks. As is also illustrated in FIG. 1, the server 104 may communicate directly with the drug delivery system 100, using a 3G or 4G antenna, for example.

**[0029]** For example, the drug delivery system 100 is illustrated as communicating with a mobile computing device 110 (e.g., a smartphone, a smartwatch, a smart wearable device, a tablet computer, etc.) via a first communication link 112, and with a computing device 114 (e.g., a personal computer or a dedicated hub) via a second communication link 116. Both links 112, 116 may operate according to, for example, a near field communication protocol, Bluetooth, and/or Bluetooth Low Energy. The mobile computing device 110 may communicate with a cellular network 118 via a communication link 120, while the other computing device 114 may communicate with a hard-wired network (e.g., local area network or wide area network) 122 via a communication link 124. These networks 118, 122 may also communicate with the server 104.

**[0030]** The networks 118, 122 may facilitate communication between the server 104 and one or more parties associated with the patient 102, such as his or her caregiver 130, support giver 132 (e.g., a family member, a friend, individual using a similar drug and/or drug delivery device as the patient 102), a healthcare provider 134, via their mobile computing devices (e.g., smartphones, smartwatches, smart wearable devices, tablet computers, etc.) and/or another computing devices. The server 104 may also be in communication with one or more computing devices (e.g., servers) associated with one or more additional parties associated with the patient 102. For example, a healthcare system server 140, a payment server 142, a pharmacy server 144, a distributor server 146, and a governmental agency server 148 are illustrated in communication with the server 104 via the network 122. It will also be recognized that the networks 118, 122 may be in communication with each other.

**[0031]** In some embodiments, the server 104 may be used to provide social networking based support for the user 102

of the drug delivery system **100**, as described below in more detail with reference to FIGS. **4** and **5**.

**[0032]** FIGS. **3A-3C** illustrate a method **300** that may be viewed as illustrating some of the mixed operational and condition state monitoring that may occur in a method and system according to the disclosure. The method **300** may also be viewed as illustrating how the one or more sensors may be used to determine the state changes described above. Furthermore, the method **300** may be viewed as providing disclosure of operational and conditions state monitoring and communication of that information not illustrated in FIG. **2**.

**[0033]** Referring first to FIG. **3A**, the method **300** may begin with the drug delivery device in the package, and the method waits at block **302** until it is determined that the package has been opened. At this point, the device may optionally be locked until such time as the system conducts one or more validations, verifications or checks to ensure that the device is ready to administer, the sterile barrier has been removed and/or the device has been (correctly) applied (see blocks **220**, **226**, **232** of method **220** in FIG. **2**). Before conducting each of the one or more validations, verifications or checks, the method **300** may determine if the drug delivery device is adapted or programmed to carry out the validation, verification or check. For example, a determination may be made at block **304** if the drug delivery device is adapted or programmed to check the sterility of the drug delivery device; in particular, the validation or verification may be related to a sterile barrier disposed at the second end of the cannula. If the drug delivery device is adapted or programmed to perform the sterility check, the method **300** may proceed to block **306**, where it is determined if the sterile barrier is disposed over or about the second end of the cannula, for example.

**[0034]** If it is determined at block **306** that the barrier is in place, then the method may proceed to block **308** where the user is instructed to remove the barrier. The method **300** may then determine at block **310** if the barrier has been removed. When it is determined that the barrier has been removed, a sterility timer may be started, the expiration of which may result in the drug delivery device being placed into or remaining in a locked state, preventing use of the drug delivery device.

**[0035]** If it is determined at block **306** that the barrier is not in place (i.e., the barrier has been prematurely removed), the method **300** may proceed to block **312**, wherein the delivery device is locked (e.g., a lock or lock-out device is actuated) or the delivery device remains in a locked state if the device was previously locked. According to certain embodiments, the locking of the delivery device at block **312** may be irreversible. According to other embodiments, including the embodiment illustrated in FIGS. **3A-3C**, the lock may be reversed once it is determined that the drug product (e.g., the drug product reservoir) has been replaced at block **314**. If the drug product is not replaced, or in those embodiments where the drug product cannot be replaced (i.e., the lock is irreversible), information regarding the failed sterility check may be communicated by the system.

**[0036]** If (i) the determination is made at block **304** that the system is adapted to validate, verify or check the sterility of the device, (ii) the determination is made at block **306** that the barrier is in place and at block **310** that the barrier subsequently has been removed, or (iii) the determination is made at block **306** that the barrier is not in place but the

determination is made at block **314** that the drug product had been replaced, the method **300** continues to block **316**. At block **316**, a determination is made if the drug delivery device is capable of performing visual and/or environmental inspections. If the device is so adapted, the method proceeds to block **318**, wherein the determination is made if the visual inspection and/or environmental conditions are within desired thresholds. If the determination is made that the visual inspection and/or environmental conditions are outside desired thresholds, then the method may proceed to blocks **312**, **314**. If the determination is made that the visual inspection and/or environmental conditions are within desired thresholds, then the method **300** may proceed to block **320**.

**[0037]** At block **320**, a determination is made whether the drug delivery system is able to confirm the user identity. If the drug delivery system is so adapted, then the method **300** continues to block **322**, and the determination is made if the user identity matches the authorization for the use of the drug delivery device. If the user is not identified as an authorized user at block **322**, then the method **300** continues to block **324**, where the drug delivery device is locked or remains locked, and block **326**, where the information regarding the attempted unauthorized use is communicated to local and/or remote devices. If the user is identified as an authorized user, then the method **300** proceeds to FIG. **3B** and block **328**.

**[0038]** At block **328**, a further determination is made as to whether the drug delivery system is enabled to confirm the temperature of the drug product. If the system is so adapted, then the method **300** continues to block **330**. At block **330**, a determination is made if the drug product temperature is within a range for predictable delivery (neither too high nor too low). If the determination is made at block **330** that the temperature is not within the range for predictable delivery, then the method **300** continues to block **332**, wherein a determination is made if the device is capable of heating or cooling the drug product to bring the temperature of the product within the range. If the system is not so adapted, then the method proceeds to block **334**, where the device may be locked or remain locked to allow passive heating or cooling to occur and the user may be alerted. Optionally, the system may also communicate the information to local and/or remote devices. If the system is enabled to permit heating or cooling, then the method proceeds to block **336**, where the device may be locked or remain locked, heating or cooling may be initiated, and the user may be alerted. Whether passive or active heating or cooling (blocks **334**, **336**), the method **300** may continue to block **338**, where delivery is delayed to provide time for the heating or cooling to occur before the method returns to block **330**. According to certain embodiments, the method **300** may terminate after block **330** (in case of excessive temperature, for example) and may communicate that information to local and/or remote devices.

**[0039]** In some embodiments, the temperature check performed at block **330** may involve an evaluation of the temperature history of the drug product to determine the range and duration of temperatures experienced by the drug product in the past (e.g., during storage, distribution, etc.). If the temperature history of the drug product is unacceptable due to, for example, the drug product being exposed to elevated temperatures for several days during shipment, the controller **350** may lockout the drug delivery device **302** so

that it cannot be used to deliver the drug product to a patient, and additionally, may control the communication module 352 to transmit a report to the local computing device 304 or the remote computing device 306 representative of the unacceptability of drug product's temperature history. In some embodiments, upon a determination that the temperature of the drug product exceeds a threshold temperature, the controller may begin a timer that runs until the temperature falls back below the threshold temperature. If the duration of the timer exceeds a predefined time limit, the controller 350 may lockout the drug delivery device 302 and control the communication module 352 to transmit a report representative of the unacceptability of drug product's temperature history.

[0040] Returning to FIG. 3B, if the determination is made at block 328 that the device is not adapted to perform a temperature check or at block 330 that the temperature of the drug product is within the desired range, then the method may continue to block 340, where a determination is made if the device is enabled to determine that the device is properly positioned on or oriented relative to the patient. If the device is so adapted, then the method proceeds to block 342, and a determination is made whether the device is properly disposed or oriented. In this regard, depending on the preferred insertion site, knowledge of the orientation of the device may be useful in providing a successful injection. For example, self-administration into the abdomen would most likely result in an orientation of an autoinjector axis approximately horizontal.

[0041] If the device is not properly disposed, then the method proceeds to block 344, and the device may be locked and the user instructed to reposition or reorient the device. The method 300 may then proceed to block 346 wherein a time delay is provided for the user to reposition the device before the method 300 returns to block 342 for a further determination relative to the position of the device. Alternatively, if the device is properly disposed, then the method may proceed to block 348, and any locks or lockouts that may have been actuated are removed (or the device is unlocked).

[0042] The method 300 continues at block 350, wherein a determination is made whether the system is enabled to determine if the delivery has been triggered. If the determination is made that the system is so adapted, then the method proceeds to block 352, and a determination is made if the device has been activated or triggered. If the determination is made at block 352 that the device has not been triggered, then the method 300 may proceed to block 354 and the system may instruct the user to trigger the device. According to other embodiments, the drug delivery device may wait for a predetermined and/or preprogrammed time delay to occur before triggering the device automatically upon the completion of the time delay. According to still other embodiments, the method 300 may optionally determine if a timer has elapsed at block 355 to reduce the risk of contamination and infection, for example. According to such embodiments, the timer may be started upon the determination that the barrier has been properly removed at block 310 (or may be started upon the determination that the barrier has been removed, according to still further embodiments), and if the method 300 does not determine that the device has been triggered within a certain amount of time from that event, the method 300 may return to block 312, for example, as illustrated in FIGS. 3B and 3A. If it is determined at block 350 that the

trigger has occurred, then the method proceeds to block 356, where the user may be notified of the triggering of the device and/or the date, time and location of the delivery may be stored or recorded. Optionally, this information may also be communicated to local and/or remote devices in communication with the system. The method 300 then continued to FIG. 3C.

[0043] A further determination may be made at block 358 whether the system is enabled to determine if the device has remained properly positioned on or oriented relative to the body. If the system is so adapted, then the method 300 continues to block 360, and a determination is made if the device is properly positioned on or oriented relative to the body. If the device is not properly positioned or oriented, then the method 300 may continue to block 362, where the user is alerted to reposition or reorient the device, and block 364, where a time delay is provided for the user to reposition or reorient the device, before returning to block 360 wherein the position or orientation of the device on the patient's body is determined. If the device is properly positioned or oriented, the method 300 may proceed to block 366. Optionally, the method 300 may repeat block 360 periodically during the time the device is administering the drug product to ensure that the device remains correctly positioned.

[0044] At block 366, a determination is made whether the system is enabled to determine if the administration is complete. If the system is so adapted, then the method 300 continues to block 368, and a determination is made if the delivery is complete. In some embodiments, it may be determined that the medicament has been successfully delivered to the patient in response to sensor data indicating that: (i) a needle shield (e.g., needle shield 526 described below) has been moved in the distal direction relative to a delivery cannula (e.g., delivery cannula 514 described below); and/or (ii) a plunger (e.g., plunger 531 described below) has completed its delivery stroke by having moved from its proximal position to its distal position. If the determination is made at block 368 that the delivery is not complete, then a further determination is made at block 370 whether the delivery can be completed. If the delivery is not complete but may be completed, then the method 300 returns to block 368 via block 372, where the device is permitted to continue to administer the drug product. If the delivery is not complete and cannot be completed (e.g., the device has been removed from the patient's skin), then the method 300 continues to block 374, and information regarding the drug and drug delivery may be communicated to a local and/or remote device. For example, information regarding whether certain operational states occurred (cannula inserted, delivery started, delivery partially completed), the timing of the operational states, and the amount of drug product that was administered may be communicated.

[0045] If the determination is made at block 368 that the delivery has been completed, then the method proceeds to block 376, where the system indicates to the user that the delivery is complete. Furthermore, the method 300 communicates information regarding the drug delivery, the drug delivery device, and the drug product to local and/or remote devices at block 378. For example, the information may include that certain operational states occurred and the timing of the operational states. The method 300 may also verify that the device was correctly positioned throughout, where the system is enabled to make this determination. The method 300 may also pass to block 378 if the system is not

enabled to determine if the administration of the drug product is complete, the assumption made that the drug delivery device having been determined to have passed through one or more of the preceding operational states necessarily leads to the conclusion that the delivery was completed.

**[0046]** Again, it should be noted that while the above description relates to a method including a series of states of the devices and alternative actions that may depend on those states, the device need not determine each and every state or perform each and every action illustrated in FIG. 3A-3C. Rather, it will be recognized that one of ordinary skill in the art may omit or eliminate the determination of certain states or performance of certain actions, so as to result in a system that may control the device based on or communicate a subset of the states described.

**[0047]** Having discussed the possible methods of operating the drug delivery system in the context of the illustrated methods of FIGS. 2 and 3A-3C, the possible methods of operating one or more computing devices in communication with the drug delivery system is now discussed in the context of a method 400 illustrated in FIG. 4. It will be recognized that the method 400 may be carried out by a single computing device, such as the server 104 illustrated in FIG. 1, or the remote computing device 506 described below in connection with FIG. 5. Alternatively, the actions discussed with respect to FIG. 4 may be carried out by multiple computing devices, such as the mobile device 110 and/or the computing device 114 in conjunction with the server 104 illustrated in FIG. 1, or the local computing device 504 and the remote computing device 506 illustrated in FIG. 5.

**[0048]** The method 400 begins at block 402 with a determination as to whether a report has been received from the drug delivery system. If no report has been received, the method 400 waits at block 402. Once it is determined that a report has been received at block 402, the method 400 proceeds to block 404.

**[0049]** At block 404, the report received from the drug delivery system is used to update one or more records. In this regard, the one or more computing devices adapted or programmed to carry out the method 400 may perform the actions of retrieving the one or more records from storage in one or more memory storage devices, writing the information received from the drug delivery device into the one or more records, and then storing the one or more records in the one or more memory storage devices. The one or more memory storage devices may be part of the one or more computing devices, may be separate from the one or more computing devices, or may include one or more of the memory storage devices that are part of the one or more computing devices and one or more memory storage devices that are separate from the one or more computing devices (i.e., the record is stored at the computing device and in backup storage separate and possibly remote from the computing device).

**[0050]** As mentioned above, the report may be used to update one or more records. For example, there may be one record for the individual patient that is stored in a patient record database. The patient record may be used, for example, to track the compliance of the individual patient (e.g., patient 102) with his or her regimen(s). There may also be a record for the drug delivery system used by the individual patient that is stored in a drug delivery system

database. The drug delivery system record may be used to store information regarding the drug delivery system throughout the life of the drug delivery system. The drug delivery system record may be accessed by the drug delivery system manufacturer or the drug provider for quality control purposes (e.g., to monitor individual instances of the drug delivery system for faults or failures attributable to the drug delivery system, or to track the environmental condition histories of one or more drug delivery systems for patterns that may assist in determining improvements in the design, packaging, shipment or handling of the drug delivery systems). There may also be record for drug used in the drug delivery system that is stored in a drug database. This record may be used in a similar fashion to the drug delivery system record for quality control purposes.

**[0051]** In addition to the updating the records at block 404, the computing device adapted or programmed to carry out the method 400 may be adapted or programmed to carry out one or more actions based on the information in the report received from the drug delivery system. For example, the computing device may be adapted or programmed to carry out an action at block 406. This action may require not only the information received in the report and/or stored previously in the record updated at block 404, but may require additional information such as from other patient records, drug system delivery records and/or drug records. If this is the case, the determination may be made at block 408 that these other records need to be accessed, and the information retrieved at block 410 (e.g., by retrieving these other records from the patient, drug delivery system and drug databases and reading the information from these records once retrieved). The action may then be carried out at block 412.

**[0052]** As one example, the one or more computing devices adapted or programmed to carry out the method 400 may be adapted or programmed to use the information received in the report to prepare a compliance history for the patient, which compliance history tracks uses of instances of the drug delivery system by the individual patient relative to his or her treatment regimen to determine how successful the patient has been in following the treatment regimen and which compliance history may be stored in the patient record. In addition, the one or more computing devices may determine if a pharmacy should be contacted to order delivery of additional drug delivery devices for the individual patient, and may generate a communication to be sent to the pharmacy to order the delivery of additional drug delivery systems. Further, the one or more computing devices may determine if a reminder should be sent to the patient, via the mobile device 110 for example, to improve or support compliance with the individual patient's treatment regime, in which case the one or more computing devices may generate a communication to be sent to the patient or user of the device. Further, the one or more computing devices may determine that the operation of the drug delivery device should be modified because of a conditional state received from the drug delivery device, for example. For example, the one or more computing devices may determine that the drug delivery system should be locked to prevent its use because of the temperature history of the drug in the drug delivery system, for example. In this case, the one or more computing devices may generate a communication, in the form of a signal for example, to be sent to the drug delivery system to lock the drug delivery device that is part of the drug delivery system. Other

possible actions are discussed in detail below, although this discussion is for illustrative purposes only and is not intended to be limiting.

[0053] Depending on the action taken at block 412, or even if it is determined at block 406 that no action need be taken, the method 400 may proceed to blocks 414, 416, 418 where determinations are made if the computing device should make contact with other parties (block 414), interact with the patient (or user, if not the same as the patient) (block 416) or control the drug delivery device that is part of the drug delivery system (block 418). For example, as discussed above, the action taken at block 412 may involve the generation of communications or signals to be sent to third parties, such as the pharmacy, to the patient, or to the drug delivery device. In such a case, the one or more computing devices may carry out the actions of block 420, 422, 424 as dictated by the determinations made at blocks 414, 416, 418. Alternatively, the one or more computing devices may carry out the actions of blocks 420, 422, 424 even if it is determined that no action need be taken at block 406. For example, the one or more computing devices may forward certain information to third parties 420 based solely on the receipt of the information in a report from the drug delivery device, such that there is no need to separately determine that an action need be taken in regard to the information received (i.e., the communication is automatically sent based on the fact that the information has been received, with the one or more computing devices acting as a repeater station for such information). The receipt of information from the drug delivery device may also prompt communications to be sent to the patient/user or control signals to be sent to the drug delivery system without a separate determination that such action need be taken, the communication or control signal being sent simply because certain information and/or reports were received from the drug delivery system.

[0054] Having made the determinations at blocks 414, 416, 418 and carried out the actions of blocks 420, 422, 424, the method 400 may return to block 402 to await the next report. It will be recognized that the one or more computing devices may perform the actions of the method 400 in parallel for each of the reports received from different instances of the drug delivery system, or may perform this steps in sequence for each report. If performed in parallel, the one or more computing devices may determine if action is to be taken in regard to one report, while the one or more computing devices may be interacting with another patient in regard to the information contained in the report received from that patient. Furthermore, the one or more computing devices carrying out the method 400 need not be adapted or programmed to carry out each of the actions described above according to every embodiment of the one or more computing devices. For example, one of the one or more computing devices may be adapted or programmed to update records for each patient and to determine if an interaction with that patient is required, while another of the one or more computing devices may be adapted or programmed to update records for each drug delivery device and to determine if a control signal should be sent to the drug delivery device, while another one of the one or more computing devices does not update any record, but is adapted or programmed to access, for example, a patient record and determine if the pharmacy needs to be contacted to order additional instances of the drug delivery system for

the patient associated with the patient record accessed and to generate the communication if the order of additional instances of the system is required.

[0055] It will be appreciated that the methods 200, 300, and 400, above, touch only a fraction of the possible state and identity information that may be used to control and/or monitor the drug delivery device and that may be communicated between the drug delivery system and the one or more computing devices, as well as how that information is used by the drug delivery system and the one or more computing devices. Additional embodiments are possible according to the disclosure.

[0056] For example, a non-limiting matrix of state and identity information may include the following:

[0057] Condition State Information:

[0058] Temperature

[0059] Shock or vibration exposure

[0060] Light exposure

[0061] Color and/or turbidity (as relates to the drug)

[0062] Orientation

[0063] Geographic position

[0064] Temporal information

[0065] Operational State Information:

[0066] Device removed from package

[0067] Device removed from cold storage (e.g., refrigerator)

[0068] Device/drug temperature ready for administration

[0069] Delivery triggered

[0070] Device applied to patient

[0071] Device applied at correct location/orientation on patient

[0072] Cannula inserted into patient and/or inserted into correct tissue

[0073] Delivery in progress

[0074] Delivery complete

[0075] Error has occurred

[0076] Device Identity Information:

[0077] Drug name or identification, concentration, and/or amount

[0078] Security and/or anti-counterfeiting information

[0079] Patient prescription/therapeutic regime

[0080] Patient Identity Information:

[0081] Point of Care diagnostics on patient

[0082] Self-analyzed measure of progress

[0083] Fingerprint, pin, or other secure identification information

[0084] This information may be used to control the drug delivery system or device, to be communicated to other computing devices, or otherwise to be used, and an exemplary listing of certain additional uses is included below. The listing and additional comments below is not intended to supersede, but to augment the discussion above, and is intended to be non-limiting.

[0085] As one example, the drug delivery system or the one or more computing devices may make a determination regarding the authenticity of the drug and its compliance with manufacturing standards. Such a determination may be made by the drug delivery device at block 220 of method 200 or block 318 of method 300, or by the one or more computing devices at block 406 of method 400, for example. The determination may be made based on the temperature, shock or vibration exposure, and/or light exposure of the drug delivery device/drug (or a history of one or more of



these conditions) and color and/or turbidity of the drug (as determined by an optical inspection). This determination may result in control of the drug delivery device to either lock or unlock the device, according to the determination made. See blocks 220, 222, 224 of method 220, blocks 318, 312, 314 of method 300, and blocks 406-412 and 418, 424 of method 400.

[0086] As another example, the drug delivery system or the one or more computing devices may make a determination whether the drug is appropriate for the patient. See block 220 of method 200, block 322 of method 300, and block 406-412 of method 400. The determination may be made based on one or more of the items of device of patient identity information listed above, and may also result in control of the drug delivery device to either lock or unlock the device, according to the determination made. See blocks 220, 222, 224 of method 220, blocks 322, 324, 326 of method 300, and blocks 406-412 and 418, 424 of method 400.

[0087] As a further example, the drug delivery system or the one or more computing devices may make a determination whether the dose has been correctly administered. This determination may be carried out after determining that the drug is appropriate for the patient and/or that the drug is authentic (e.g., not counterfeit) and is in compliance with manufacturing standards. See the preceding paragraphs. The determination whether the dose has been correctly administered may depend on one or more of the types of operational state information listed above. See blocks 220-260 of method 200, and blocks 328-378 of method 300. This information may be used to update the patient record, determine the patient compliance or therapy progress, and may prompt communication with the pharmacy regarding a refill, or with the payer (e.g., insurance company) to authorize payment for the drug delivery device. See blocks 404-414 of method 400, and servers 142, 144 of FIG. 1.

[0088] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination regarding the operational state of the drug delivery device, and to generate instructional messages to guide the user through the actions required for the proper use of the drug delivery device. The determination may be based on any of the operational state information listed above, and the instructions generated may be dictated by the actions that need to be performed after the operational state that has just occurred. Implementation of interactive instructions that follow the changing states of the drug delivery device may help the user have confidence in administration of the drug.

[0089] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the patient needs more medication (a refill). See blocks 406-412 of method 400. The determination may be based in part on the drug identity information, such as the prescribed treatment regime, and in part on the operational state information, such as where the drug delivery has been completed. Based on this information, the one or more computing devices may generate a communication that is sent to the payer and/or pharmacy to request a prescription refill. See blocks 414, 420 of method 400.

[0090] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that the injection was not performed

correctly. See blocks 406-412 of method 400. The determination may be based in part on operational state information, in comparison with information that may be collected and stored regarding conventional norms in operation. Alternatively or additionally, a comparison between the determined, reported or received operational states may permit a determination to be made that the injection was not performed correctly. For example, the determination, reporting or receipt of operational state information indicating that the drug delivery is complete without operation state information indicating that device was triggered, that the device was applied to the patient, and/or that the cannula was inserted may indicate that the drug delivery device has failed to perform correctly, is faulty or was operated incorrectly.

[0091] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that patient's condition is improving. The determination may be based in part on patient identity information, such as point-of-care diagnostics performed on the patient (e.g., blood glucose test or other testing) or self-analysis reporting, and in part on the determination, reporting or receipt of operational state information, such as where the drug delivery has been completed. The determination may rely upon an overall trend as opposed to individual determinations or reports, as it is believed that data or reporting trends are usually more indicative of improvement in a patient's condition than the patient's condition as determined at individual instances for serious diseases. As such, the information gathered regarding the patient and the operational state of the drug delivery system/device may be combined with combined with therapy compliance history. This determination may result in individualized interventions to be generated, which interventions (such as encouraging messages and other forms of positive reinforcement) may increase persistence in therapy.

[0092] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination of the time of day (or week, month, etc.) that the patient usually takes their medication. This determination may be based, in part, on the patient record in which time information is associated with operational state information, such as relates to the triggering of the drug delivery device or the completion of the drug delivery. This determination may also rely on device identity information, such as the prescribed treatment regimen. Based on this determination, the one or more computing devices may generate a reminder communication that is sent, for example, to the mobile device 110 to alert the patient that the time is approaching for them to administer their next dose. As the usefulness of reminders is enhanced when there is reasonable access to the drug delivery device and an opportunity for its use, it is beneficial to reinforce a patient's decision to take their medication at a particular time during the day, week, month, etc. Based on this determination, the one or more computing devices may also generate a personalized intervention, such as a message of encouragement to be used as a positive reinforcement.

[0093] As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination where the patient usually takes their medication. This determination may be based, in part, on the patient record in which geographic position information is associated with operational state information, such as relates to the triggering of the drug delivery device or the comple-

tion of the drug delivery. This determination may also rely on device identity information, such as the prescribed treatment regimen. Based on this determination, the one or more computing devices may generate a reminder communication that is sent, for example, to the mobile device **110** to alert the patient that the time is approaching for them to administer their next dose when they are at or near the geographic location where the patient usually uses the drug delivery system. As the usefulness of reminders is enhanced when there is reasonable access to the drug delivery device and an opportunity for its use, it is beneficial to reinforce a patient's decision to take their medication when they are in the usual location where they take their medication. Based on this determination, the one or more computing devices may also generate a personalized intervention, such as a message of encouragement to be used as a positive reinforcement.

**[0094]** Of course, the determinations regarding the usual time and location of the use of the drug delivery device may be combined, and the one or more computing devices may generate a message only when the patient or user is at or near their usual location of use at or near the time they usually use the drug delivery device.

**[0095]** As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination that other people nearby are taking the same medication. See blocks **406-412** of method **400**. This determination may be made based on the drug identity information and the patient identity information, in combination with the drug delivery system geographic location information. This determination may prompt a communication with the patient (see blocks **416, 422** of method **400**) regarding local support networks of persons with similar conditions and/or taking similar drugs or medication to permit the patient to receive support and encouragement from such networks. Alternatively, the determination may prompt a communication with the local support network(s) (see blocks **414, 420** of method **400**) requesting them to support and encourage to the patient. As a further alternative, the determination may prompt a personalized intervention communication to be sent to the patient (again, see blocks **416, 422** of method **400**).

**[0096]** As a further alternative, the drug delivery system or the one or more computing devices may use the information to make a determination whether the patient is not in compliance with their treatment regimen. See blocks **406-412** of method **400**. The determination may be based in part on the drug identification information, such as the prescribed treatment regime, in part on condition state information, such as the passage of time, and in part on the operational state information, such as where the drug delivery device is removed from the packaging but where no additional operational state information is determined, reported or received during the passage of time from the removal from packaging operational state. Based on this information, the drug delivery system and/or the one or more computing devices may determine that an interaction with the patient should be generated, such as an alert may be displayed or sent to patient. See blocks **416, 422** of method **400**. Furthermore, the drug delivery system and/or one or more computing devices may determine that a communication should be generated to be displayed or sent to a healthcare provider, caregiver, support giver and/or payer to encourage adherence to the treatment regime. See blocks **414, 420** of method **400**.

**[0097]** Described below with reference to FIGS. **5** and **6** are embodiments of a system and method for implementing the patient support network mentioned above in connection with FIG. **4**.

**[0098]** FIG. **5** illustrates an embodiment of a system **500** including a drug delivery device **502**, a local computing device **504** and a remote computing device **506**. While the system **500** includes both a local computing device **504** and a remote computing device **506**, not all embodiments according to this disclosure include both a local computing device **504** and a remote computing device **506**. Also, any one of the drug delivery device **502**, the local computing device **504** and the remote computing device **506** may be substituted for a corresponding element of FIG. **1**. For example, the drug delivery device **502**, the local computing device **504**, and the remote computing device **506** may be substituted for, respectively, the drug delivery system **100**, the mobile device **110**, and the server **104** of FIG. **1**.

**[0099]** The drug delivery device **502** may be in the form of an autoinjector, and thus is adapted for hand-held use and application against the skin of the patient. The drug delivery device **502** includes a housing **510** in which are disposed assemblies or structures that introduce a delivery cannula into the patient, and that eject a drug or medicament from a reservoir **512** through the delivery cannula into the patient. According to certain embodiments, the same assemblies or structures that introduce the delivery cannula into the patient may also eject the drug or medicament from the reservoir through the delivery cannula into the patient. The drug delivery device **502** may also include assemblies or structures that connect the delivery cannula to the reservoir, that withdraw the delivery cannula into the housing **510** through an opening in the housing **510** (not illustrated), or that deploy other structures that will prevent contact with the delivery cannula once the delivery cannula has been removed from the patient. Even additional assemblies and structures are possible. The specific embodiment of the drug delivery device **502** discussed below is thus by way of example and not by way of limitation.

**[0100]** Accordingly, the drug delivery device **502** includes a reservoir **512** and a delivery cannula **514** having a first end **516** (e.g., a proximal end) that may be connected or connectable in fluid communication with the reservoir **512** and a second end **518** (e.g., a distal end) that may be inserted into a patient. The delivery cannula **514** may be, for example, a rigid needle having a beveled edge that may be sized such that the second end **518** of the needle **514** is received under the skin so as to deliver a subcutaneous injection of the medicament within the reservoir **512**. The first end **516** of the needle **514** may be disposed through a wall **520** of the reservoir **512**, and thus be connected in fluid communication with the reservoir **512**. Alternatively, the first end **516** of the needle **514** may be disposed only partially through the wall **520** (which wall **520** may be a resalable septum or stopper, for example) such that the first end of the needle **514** may not be connected in fluid communication until the second end **518** of the needle **514** is inserted into the patient. In such a circumstance, the first end **516** of the needle **514** may thus be described as connectable in fluid communication with the reservoir **512**, although it will be recognized that there are other mechanisms by which the first end **516** of the needle **514** may be connectable, but not connected, in fluid communication with the reservoir **512**.

[0101] The drug delivery device 502 includes a shield 522 (e.g., a needle shield) that may be deployed at least after the injection has been completed to limit access to the second end 518 of the needle 514. According to certain embodiments, the shield 522 may have a biasing element 524 (such as a spring) that extends the shield 522 from the housing 510 such that a distal end 526 of the shield 522 extends beyond the second end 518 of the needle 514 except when the shield 522 is disposed against the skin and the insertion of the needle 514 is actuated. In fact, the insertion of the needle 514 may be actuated according to certain embodiments of the drug delivery device 502 by disposing the distal end 526 of the shield 522 on or against the skin of the patient.

[0102] The drug delivery device 502 may also include a lock 528 (e.g., a ratchet) that is coupled to the shield 522 and configured to limit or prevent movement of the shield 522 relative to the housing 510 of the drug delivery device 502 such that the distal end 526 of the shield 522 extends from the housing 510 a sufficient distance to limit or prevent contact with the second end 518 of the needle 514, for example, after the needle 514 has been removed or separated from the skin of the patient. In some embodiments, the lock 528 may be coupled to a controller (e.g., controller 550 described in more detail below) which can selectively activate or deactivate the lock 528 based on different types of information regarding the drug delivery device 502, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. When the lock 528 is activated by the controller 550, the lock 528 may be configured to limit or prevent movement of the needle shield 522 relative to the housing 510. When the lock 528 is deactivated by the controller 550, the lock 528 may be configured to allow movement of the needle shield 522 relative to the housing 510.

[0103] The drug delivery device 502 also includes at least one drive 530 that may be used to insert the second end 518 of the needle 514 into the skin of the patient, and to eject the drug or medicament from the reservoir 512 through the delivery cannula 514 into the patient. The drive 530 may include one or more springs, according to certain embodiments. According to other embodiments, the drive 530 may include a source of pressurized gas or a source of a material that undergoes a phase change, such that the escaping gas or phase changing material provides a motive force that may be applied to the reservoir 512 to eject the drug therefrom. According to still other embodiments, the drive 530 may include an electromechanical system, such as may include a motor for example, although such an electromechanical system may be more appropriate for the on-body autoinjector or infuser described above. Other embodiments of the drive 530 are also possible.

[0104] In one embodiment, the drive 530 may be coupled to a plunger 531 and/or a stopper 532 (e.g., a wall) disposed in the reservoir 512 to move that stopper 532 in a distal direction toward the delivery cannula 514. In accordance with such an embodiment, the stopper 532 may be a stopper that is fixed to a distal end of the plunger 531 and received within a bore 534. The plunger 531, in conjunction with the drive 530, may move the stopper 532 along a longitudinal axis of the drug delivery device 502 through the bore 534 from a proximal end of the bore 534 to a distal end of the bore 534, and thereby eject the medicament from the reservoir 512.

[0105] In some embodiments, the drive 530 may also cooperate with the stopper 532 and/or the bore 534 to move the reservoir 512 relative to the housing 510 so as to move the second end 518 of the needle 514 relative to the housing 510 and into the patient. According to those embodiments wherein the drive 530 cooperates with the stopper 532, this may occur before the first end 516 of the needle 514 is in fluid communication with the reservoir 512. According to those embodiments wherein the drive cooperates with the bore 534, the drive may include one component (e.g., first spring) that cooperates with the bore 534 to move the reservoir 512 and needle 514 relative to the housing 510, and a second component (e.g., second spring) that cooperates with the stopper 532 to move the stopper 532 relative to the bore 534.

[0106] The drug delivery device 502 may also include a lock 535 that is coupled to the plunger 531 and configured to limit or prevent movement of the plunger 531 relative to the housing 510 of the drug delivery device 502 so that the stopper 532 cannot be advanced to discharge the medicament from the reservoir 512 to the patient. In some embodiments, the lock 535 may be coupled to a controller (e.g., controller 550 described in more detail below) which can selectively activate or deactivate the lock 535 based on different types of information regarding the drug delivery device 502, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. When the lock 535 is activated by the controller 550, the lock 535 may be configured to limit or prevent movement of the plunger 531 relative to the housing 510. When the lock 535 is deactivated by the controller 550, the lock 535 may be configured to allow movement of the plunger 531 relative to the housing 510.

[0107] The drive 530 may be associated with an actuator 540. The actuator 540 may activate the drive 530 to cause the drive 530 to insert the needle 514 and eject the drug from the reservoir 512 through the needle 514 into the patient. The actuator 540 may, according to certain embodiments, be the needle shield 522, as explained above. According to other embodiments, such as the one illustrated in FIG. 5, the actuator 540 may be a button that may be manually depressed by the user or patient once the drug delivery device 502 is placed disposed on or against the patient's skin. A lock 541 may be coupled to the actuator 540 and configured to limit or prevent movement of the actuator 540 so that the actuator 540 cannot be used to activate the drive 530. In some embodiments, the lock 541 may be coupled to a controller (e.g., controller 550 described in more detail below) which can selectively activate or deactivate the lock 541 based on different types of information regarding the drug delivery device 502, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. When the lock 541 is activated by the controller 550, the lock 541 may be configured to limit or prevent movement of the actuator 540 relative to the housing 510. When the lock 541 is deactivated by the controller 550, the lock 541 may be configured to allow movement of the actuator 540 relative to the housing 510.

[0108] The drug delivery device 502 may also include a removable sterile barrier 544 that is disposed about one or more of a distal end of the housing 510, the needle shield 522, and the second end 518 of the delivery cannula 514.

The removable sterile barrier **544** may be removably attached to the distal end of the housing **510** as shown in FIG. **5**. In some embodiments, the removable sterile barrier **544** may form an interference or snap fit with the distal end of the housing **510**. A frictional force associated with the interference or snap fit may be overcome by manually pulling the removable sterile barrier **544** in a direction away from a housing **510**. The removable sterile barrier **544**, when attached to the drug delivery device **502**, may reduce the risk of contamination of the delivery cannula **514** and other elements disposed within the drug delivery device **502**.

[**10109**] Additionally, the drug delivery device **502** may include a heating element **546** coupled to the exterior of the reservoir **512** and configured to warm the medicament inside the reservoir **512** through, for example, conductive heating. The heating element **546** may be coupled to the controller **550** so that the controller **550** can selectively activate or deactivate the heating element **546** based on different types of information regarding the drug delivery device **502**, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. In some embodiments, the heating element **546** may include an electrically conductive coil that is wrapped around the exterior of the reservoir **512**. Alternatively, or additionally, a cooling element (not illustrated) may be coupled to the reservoir **512** and controllable by the controller **550** in a manner similar to the heating element **546**.

[**10110**] The drug delivery device **502** may also include an output unit **547** coupled to the housing **510** and configured to notify the patient or user of information related to the drug delivery device **502**. The output unit **547** may be coupled to the controller **550** so that the controller **550** can selectively activate or deactivate the output unit **547** based on different types of information regarding the drug delivery device **502**, including operational state information, condition information, and/or identity information, in accordance with one or more of the methods described above. The output unit **547** may be any device suitable for conveying information to the patient or user including a display (e.g., a liquid crystal display), a touchscreen, a light (e.g., a light emitting diode), a vibrator (e.g., an electro-mechanical vibrating element), a speaker, and/or an alarm, among other devices.

[**10111**] The drug delivery device **502** may also include an input unit **548** coupled to the housing **510** and configured to allow a user or patient to input information (e.g., password information) to be used by the controller **550**. In some embodiments, the input unit **548**, the output unit **547**, and even the fingerprint sensor **565**, may be a single device such as a touchscreen. In other embodiments, the input unit **548** may be a separate device from the output unit **547** such as a keyboard or button.

[**10112**] As illustrated in FIG. **5**, the reservoir **512**, the biasing element **524**, the locks **528**, **535**, **541**, the plunger **531**, the stopper **532**, and the drive **530**, and the heating element **546** are disposed within the housing **510**, along with at least part of the delivery cannula **514**. Also disposed within the housing **510** is a controller **550**, a communication module **552** (e.g., a wireless transmitter), and at least one sensor or switch. According to the embodiment illustrated in FIG. **5**, four sensors are included: a temperature sensor **560**, a skin sensor **562**, at least one orientation sensor **564**, and a fingerprint sensor **565**. The sensors **560**, **562**, **564**, and **565** may each generate sensor data (e.g., raw or unprocessed

data) related to a respective measured property or aspect of the drug delivery device **502**. The sensor data may be representative of at least one of a condition or operational state of the drug delivery device **502**. Additionally, the drug delivery device **502** includes a switch **566**. The controller **550** is coupled to the communication module **552**, the locks **528**, **535**, **541**, the sensors **560**, **562**, **564**, **565**, the heating element **546**, the fingerprint sensor **565**, the output unit **547**, the input unit **548**, and the switch **566**. The controller **550** may be configured to process the sensor data generated by the sensors **560**, **562**, **564**, and **565** to determine a condition and/or operational state of the drug delivery device **502**. The controller **550**, the communication module **552**, one or more of the sensors **560**, **562**, **564**, **565** and the switch **566** may be packaged together as a single module, or each component may be fabricated separately and coupled once the components are disposed within the housing **510**. According to certain embodiments, each electrical component may be integrated into the structure of the device **502** associated with that electrical component (e.g., the sensors **562** and **564** may be integrated into the shield **522**). In some embodiments, the controller **550**, the communication module **552**, one or more of the sensors **560**, **562**, **564**, **565**, and/or the switch **566** may be packaged together inside the removable sterile barrier **544**.

[**10113**] The controller **550** may include at least one processor **570** (e.g., a microprocessor) and a memory **572** (e.g., a random access memory (RAM), a non-volatile memory such as a hard disk, a flash memory, a removable memory, a non-removable memory, etc.). The controller **550** may also include or be coupled to a power supply, e.g. a battery. The processor **570** may be programmed to carry out the actions that the controller **550** is adapted to perform and the memory **572** may include one or more tangible non-transitory readable memories having executable, computer-readable, non-transitory instructions stored thereon, which instructions when executed by the at least one processor **570** may cause the at least one processor **570** to carry out the actions that the controller **550** is adapted to perform. Alternatively, the controller **550** may include other circuitry that carries out the actions that the controller is adapted to perform.

[**10114**] The memory **572** may store the identity information discussed above. The identity information may be stored in the memory **572** prior to the start of execution of any of the methods discussed above. The identity information may include, by way of example and not by way of limitation, a unique identifier, the name of the drug, the dosage, an expiration date, and information regarding the identity of the patient for whom the drug was prescribed. With this information, the controller **550** or a local computing device (e.g., a smartphone) may make a determination regarding the patient that is about to receive the drug, and provide appropriate informational and/or instructional prompts. As an alternative to memory **572**, the identity information may be contained in a QR code label or RFID tag associated with the drug delivery device **502**.

[**10115**] The communication module **552** may be any of a number of different communication modules used to communicate with a local computing device (e.g., a smartphone) and/or a remote computing device (e.g., a server operated by the device manufacturer). According to one embodiment, the communication module **552** may be a Bluetooth and/or Bluetooth Low Energy module that is on-board with the controller **550**. The communication module **552** is used to

transmit information from the drug delivery device **502** to the local computing device **504**. Alternatively, other wireless protocols may be used by the communication module **552**, such as radio-frequency identification (RFID), Zigbee, Wi-Fi, near field communication (NFC), and others. In fact, the communication may be sent along a hardwired connection, rather than using the electromagnetic (EM) spectrum. As defined herein, a communication transmitted and/or received between the module **552**, the local computing device, and/or the remote computing device may be in the form of a hardwired signal or EM signal or a pattern of such signals, for example.

**[0116]** The temperature sensor **560** may be disposed proximate to the reservoir **512** so that the temperature of the drug in the reservoir **512** may be determined. Alternatively, the temperature sensor **560** may simply be disposed in the housing **510**, so that an approximate temperature of the drug in the reservoir **512** and of the drug delivery device **502** generally may be determined. According to an embodiment, the temperature sensor **560** may be an on-board temperature sensor **560** attached to the processor **570**.

**[0117]** The skin sensor **562** may be attached to or associated with the shield **522** to determine when the drug delivery device **502** is disposed on or against the patient's skin. According to one embodiment, the skin sensor **562** is a pressure sensor. According to other embodiments, the skin sensor **562** may be a capacitance sensor, resistance sensor, or inductance sensor. The skin sensor **562** or the switch **566** (which is attached to or associated with the actuator **540**) may be used to determine when the drug delivery device **502** is activated or actuated, depending on the design and operation of the drug delivery device **502** that is used to actuate the drive **530**, in accordance with the discussion above. It may also be the case that a signal from the skin sensor **560** is used to determine that the drug delivery device **502** has been activated even when the shield **522** is not used as the actual actuator, the underlying assumption being that the movement of the shield **522** is necessarily related to the actuation of the device **502**.

**[0118]** The orientation sensors **564**, of which there may be at least two as illustrated, may be associated with the shield **522** (or that portion of the housing **510** adjacent the shield **522**) and the controller **550** (which may be, as illustrated, disposed at the other end of the drug delivery device **502** or the housing **510** from the shield **522**). The orientation sensors **564** may be magnetometers, for example. In particular, the orientation sensor **564** associated with the controller **550** may be an on-board magnetometer. The orientation sensors **564** may be used to determine the orientation of the drug delivery device **502** (in particular, the housing **510**) relative to the injection site (or more particularly, relative to the placement of the drug delivery device **502** on or against the patient's skin).

**[0119]** Still referring to FIG. 5, the local computing device **504** may be in the form of at least one computing device including at least one processor **620** (e.g., microprocessor) and a memory **622** (e.g., a random access memory (RAM), a non-volatile memory such as a hard disk, a flash memory, a removable memory, a non-removable memory, etc.). The at least one processor **620** and the memory **622** may be incorporated into a controller **623** of the local computing device **504** and/or may be configured separately. Likewise, the remote computing device **506** may be in the form of at least one computing device including at least one processor

**624** (e.g., microprocessor) and memory **626** (e.g., a random access memory (RAM), a non-volatile memory such as a hard disk, a flash memory, a removable memory, a non-removable memory, etc.). The at least one processor **624** and the memory **626** may be incorporated into a controller **627** of the local computing device **504** and/or may be configured separately. The processors **620**, **624** may be programmed to carry out actions described below relative to the method of FIG. 6 and the memories **622**, **626** may include one or more tangible, non-transitory computer-readable memories having computer-executable instructions stored thereon, which instructions when executed by the processors **622**, **624** may cause the processors **622**, **624** to carry out the actions described below relative to the method of FIG. 6.

**[0120]** In some embodiments, the computer-executable instructions may be included in a software application (e.g., a mobile software application, also commonly referred to as a "mobile app") stored in the memory **622** of the local computing device **504**. The software application may be installed on local computing device **504** as one or more downloaded files, such as an executable package installation file downloaded from a suitable application store via a connection to the Internet. Examples of package download files may include downloads via the iTunes store, the Google Play Store, the Windows Phone Store, downloading a package installation file from another computing device, etc. The software application may be developed for a mobile operating system such as Android™ or iOS®, developed by Google and Apple, respectively. In some embodiments, the application may be initiated by a user selecting an icon shown on a home screen of a display **632** (e.g., a touchscreen) of the local computing device **504**. Various displays, including messages received from a support group, may be generated in the application and displayed to a user and/or patient via the display **632** of the local computing device **504**.

**[0121]** According to certain embodiments of this disclosure, the local computing device **504** may carry out the actions of FIG. 6 independent of the remote computing device **506**. According to other embodiments, the local computing device **504** may carry out certain of the actions of FIG. 6, while the remote computing device **506** carries out other of the actions of FIG. 6. For example, according to certain embodiments the processor(s) **620** may control components of the local computing device **504** permitting communication with the controller **550** and/or the user, but may not make the determinations as to the content of those communications, the determinations relative to the content of the communications being made at the remote computing device **506**.

**[0122]** According to the illustrated embodiment, the local computing device **504** is a mobile computing device (e.g., a smartphone, a smartwatch, a smart wearable device, a personal computer, a laptop computer, or a tablet computer, etc.) while the remote computing device **506** is a server. In some embodiments, the local computing device **504** can include generally any computing device capable of processing data and being synched to and in communication with the drug delivery device **502** such as, for example, a smart wearable device, a personal computer, a laptop computer, a smart television, a smart appliance, a smart automobile, a networked computer, etc. According to other embodiments, the local computing device **504** may be a dedicated device such as a hub or gateway that can establish a communication

link with the communication module 552 and potentially the remote computing device 506, where communication with the remote computing device 506 is necessary or desirable.

[0123] To carry out the actions of the methods described in FIG. 6, the local computing device 504 may further include a communication module 630 for wireless communication with the communication module 552 of the drug delivery device 502, for example by using Bluetooth or Bluetooth Low Energy protocol. Alternatively, other wireless protocols may be used by the communication module 552, such as radio-frequency identification (RFID), Zigbee, Wi-Fi, near field communication (NFC), and others. The local computing device 504 may also include the display 632 (e.g., a touchscreen) to be used to display information (e.g., instructional prompts and/or informational prompts) to the user. The local computing device 504 may include other output devices other than the display 632 to communicate with the user, such as a speaker 634 for example. The speaker 634 may be controlled by the processor(s) 620 to provide an audible form of the instructions displayed in written form on the display 632.

[0124] The local computing device 504 may also include one or more communication modules, which may be the same as or different from the communication module 630, that may be used to communicate with one or more networks 640, 642. For example, the network 640 may be a wireless radio frequency network, such as a cellular mobile device network, while the network 642 may be a network of computing devices, such as the Internet. As is illustrated in FIG. 6, the networks 640, 642 may be in communication with each other, such that the local computing device 504 may communicate with the remote computing device 506 over the network 640, the network 642 or a combination of the networks 640, 642. The remote computing device 624 may include a communication module 636 to receive communications from the networks 640, 642.

[0125] While the terms “local” and “remote” have been used to describe the local computing device 504 and the remote computing device 506, these terms have not been selected to require a particular spatial or geographical distance between the devices 504, 506. Instead, the terms have been used to suggest a relative proximity to the user, and the fact that the remote computing device 506 is not required to be at the same physical location as the user and the drug delivery device 502. According to certain embodiments, it is possible, even likely, that the remote computing device 506 may be located in a different geographic location than the user and the drug delivery device 502, for example a different city, state or country.

[0126] Also, it is noted that each of the local computing device 504 and the remote computing device 506 is separate from, and spaced apart from, the drug delivery device 502, and therefore each may be considered to be an “external computing device” relative to the drug delivery device 502.

[0127] Turning to FIG. 6, illustrated is a flow diagram of one embodiment of a method 700 of providing social support to a patient associated with the drug delivery device 502. The memory 622 of the local computing device 504 and/or the memory 626 of the remote computing device 506 may store one or more computer-executable instructions that, when executed by the processor 620 of the local computing device 504 and/or the processor of the 624 of the remote computing device 506, cause the processor 620 of the local computing device 504 and/or the processor of the

624 of the remote computing device 506 to carry out the actions described below relative to the method 700. Also, as described below in more detail, the method 700 may leverage social networking services (e.g., Facebook, Twitter, etc.) that provide access to groups of users who are already connected, or who can easily be connected, to the patient. By providing the patient with support (e.g., encouragement, praise, coaching, advice, reminders, etc.), the patient may be more likely to comply with a treatment regimen (e.g., a therapeutic regimen) for treating a medical condition of the patient with drug delivery device 502.

[0128] The method 700 may begin with associating the patient with a support group or multiple support groups (see block 710). The support group may be a group of people and/or organizations having an interest in the patient complying with the treatment regimen. The support group may include a healthcare provider (e.g., a doctor, nurse, etc.), a caregiver, a family member, a friend, a medical device manufacturer, an insurance company, and/or another individual using a similar drug delivery device and/or having a similar medical condition. In some embodiments, the support group may be a pre-existing online community of individuals connected through a social networking service, such as a Facebook group. In some embodiments, the support group may consist of the patient's Facebook friends.

[0129] The association of the patient with the support group may be accomplished in a variety of different manners. In some embodiments, the patient may select (via, for example, a mobile application executing on the local computing device 504) a pre-existing group (e.g., the patient's Facebook friends) to be the support group. The patient's selection may be transmitted to the remote computing device 506 which subsequently associates the patient with the patient-selected support group. In other embodiments, the remote computing device 506 may register identity information about the patient (e.g., age, height, weight, medical condition, etc.) and then associate the patient with individuals sharing similar identity information. In still further embodiments, the associating the patient with a support group may include initially collecting data (e.g., GPS data) from the local computing device 504 about the geographic location of the patient and/or the drug delivery device 502. Based on this data, the remote computing device 506 may choose individuals who are physically near the geographic location of the patient as the support group. The geographic-based method of associating the patient with a support group may be combined with any of the foregoing methods of association, such that the geographic location of the patient is only one factor in the selection of an appropriate support group. In some embodiments, the patient may be presented with map of nearby support groups from which the patient can select a desired support group.

[0130] Next, the method 700 may involve receiving, at the local computing device 504 and/or at the remote computing device 506, data representative of a condition and/or an operational state of the drug delivery device 502 (see block 720). The data may be in the form of one or more of the reports similar to those described above in connection with the method 200 and/or the method 300. In some embodiments, the drug delivery device 502 may transmit sensor data, collected by the sensors onboard the drug delivery device 502, to the local computing device 504, which in turn, may analyze the sensor data to generate a report representative of a condition and/or an operational state of

the drug delivery device **502** and then transmit that report to the remote computing device **506**. In other embodiments, the sensor data may be transmitted directly to the remote computing device **506**, which may then analyze the sensor data to determine the condition and/or operational state of the drug delivery device **502**. In still further embodiments, the drug delivery device **502** may analyze the sensor data and generate the report representative the condition and/or an operational state of a drug delivery device **502**, and then transmit that report to the local computing device **504** and/or the remote computing device **506**.

**[0131]** Once in possession of the data representative of the condition and/or the operational state of the drug delivery device **502**, the local computing device **504** and/or the remote computing device **506** may analyze the data to determine if the patient has complied with a treatment regimen (see block **730**). This determination may involve a comparison of the data representative of the condition and/or the operational state of the drug delivery device **502** with a predefined criteria stored in the memory **622** of the local computing device **504** and/or the memory **626** of the remote computing device **506**. The predefined criteria may specify, for example, the frequency with which the patient is to receive an injection of a medicament, the amount or dose of medicament to be received by the patient, the temperature of the medicament at the time of injection, the type of medicament to be received by the patient, and/or the sequence in which a medicament is to be injected along with other medicaments. In some embodiments, the predefined criteria may indicate that the patient is to receive an injection of the medicament every day before noon.

**[0132]** In some embodiments, compliance with the treatment regimen may be involve a determination that the operational state of the drug delivery device **502** corresponds to the drug delivery device **502** having completed delivery of the medicament to the patient. Judging whether delivery of the medicament to the patient has been successful may accomplished in a manner consistent with the method **200** and/or the method **300**. In some embodiments, successful drug delivery may be determined if both the needle shield **522** has been moved in the distal direction relative to the delivery cannula **514** and the plunger **531** has completed its delivery stroke by moving from its proximal position to its distal position. Other conditions or states that may be considered to confirm successful delivery of the medicament to the patient include an indication that the actuator **540** has been triggered (e.g., depressed) and/or the amount of medicament remaining in the reservoir **512**.

**[0133]** In response to a determination at block **720** that the patient's use of the drug delivery device **502** complies with the treatment regimen, the method **700** may return to block **720**, where the local computing device **504** and/or the remote computing device **506** waits for the reception of new data representative of at least one of a condition or an operational state of a drug delivery device **502**. In an alternative embodiment (not illustrated), in response to a determination at block **720** is compliant with the treatment regimen, the local computing device **504** and/or the remote computing device **506** may transmit a communication to the support group associated with the patient requesting the support group to send a message of praise or congratulation to the patient.

**[0134]** In response to a determination at block **720** that the patient is not compliant with the treatment regimen, the local

computing device **504** and/or the remote computing device **506** may transmit a communication to the support group associated with the patient in order to initiate an intervention with the patient (see block **740**). The communication may be sent through a social networking service or some other mechanism (e.g., email, SMS message, push notification, telephone, etc.). The communication may request the support group to counsel the patient about the treatment regimen. In some embodiments, the request may suggest that the support group send a message to the patient encouraging the patient to comply with the treatment regimen. In some embodiments, the request may include pre-written message and/or an ideogram (e.g., an emoji) which can be sent, on demand, by a member of the support group to the patient. In addition to asking the support group to counsel the patient, the request may ask the support group to actively intervene by, for example, meeting with the patient in-person, physically assisting the patient with their use of the drug delivery device, and/or actually administering the medicament to the patient with the drug delivery device. Active intervention may be especially beneficial for patients suffering from dementia and other forms of cognitive decline. In some embodiments, the message asking the support group to intervene may include an indication of the patient's limited cognitive abilities so that the support group appreciates the patient's vulnerability to forget their medication schedule.

**[0135]** Next, the method **700** may include the local computing device **504** and/or the remote computing device **506** receiving a communication from the support group providing the requested counseling (see block **750**). The communication may in the form of a message sent through a social networking service or some other mechanism (e.g., email, SMS message, push notification, telephone, etc.). The message may include words of encouragement, coaching, advice, a reminder, or any other communication likely to urge the patient to comply with the treatment regimen.

**[0136]** After receiving the communication from the support group, the method **700** may forward the communication to the patient (block **760**). This may involve displaying the communication on the display **632** of the local computing device **504** and/or generating a sound with the speaker **634** of the local computing device **504**.

**[0137]** In general, the support provided to the patient by the method **700** is reactive support since it is provided in response to the patient's failure to comply with the treatment regimen. In addition to reactive support, or as a substitute for reactive support, the methods and systems disclosed herein may be configured to provide the patient with proactive support. This type of support reduces the likelihood that the patient will fail to comply with the treatment regimen by taking preventative measures before a violation of the treatment regimen occurs. In one implementation, the local computing device **504** and/or the remote computing device **506** may evaluate the treatment region to determine if the patient is scheduled to receive a dose of the medicament in the near future (e.g., tomorrow, tonight, in the next hour, etc.). In response to a determination that the patient is scheduled to receive a dose of the medicament, the local computing device **504** and/or the remote computing device **506** may transmit a communication to the support group associated with the patient. This communication may include a request for support group to remind the patient to take their upcoming dose of the medicament. Similar to the method **700**, these steps may be performed by executing

non-transitory, computer-executable instructions included in a mobile software application, or other module, stored in the memory 622 of the local computing device 504 and/or the memory 626 of the remote computing device 506. Upon receipt of the communication asking for support, members of the support group may send one or more messages through a social networking service or some other mechanism (e.g., email, SMS message, push notification, telephone, etc.) to the patient reminding him or her to take their medication. By providing the patient with proactive support, the patient may be less likely to miss a scheduled dose of the medicament.

**[0138]** Additionally, while the foregoing embodiments provide support that is not actively solicited by the patient, the scope of the present disclosure is not limited to unsolicited support. In some embodiments, the local computing device 504 and/or the remote computing device 506 may be configured to receive a request from the patient for help and/or support, and in response to that request, automatically contact an appropriate individual or organization. In one implementation, a mobile software application executing on the local computing device 504 may display a help button or icon that, when selected by the patient, causes the local computing device 504 to transmit a help request to a healthcare provider (e.g., doctor, nurse practitioner, nurse, etc.), caregiver, medical device manufacturer, support group, or any other individual or organization capable helping the patient. The help request may solicit technical support for proper use of the drug delivery device, emotional support, information about the medicament and its side effects, and/or any other type of support. In an embodiment where the local computing device 504 is a smartphone, selecting the help button may cause the smartphone to automatically call a support hotline, call a member of a support group, and/or open a website (e.g., a website including a list a frequently asked questions) in a web browser executing on the smartphone. Accordingly, the patient may be able to obtain immediate support for his or her questions or concerns.

**[0139]** In addition to the various medical benefits discussed above, the methods and systems disclosed herein have several technical effects on the process of monitoring the use of a drug delivery device and ensuring patient compliance with a treatment regimen. One technical effect is the computer-implemented determination of the condition and/or operational state of the drug delivery device and the automatic distribution of this information to a social network for further processing and/or notification of a support group. Accordingly, a caregiver is not required to manually determine, or manually notify a support group of, the condition and/or operational state of the drug delivery device to ensure patient compliance. Another technical effect is that the presently disclosed systems and methods streamline the process of identifying an appropriate support group for the patient. For example, the systems and methods may automatically associate the patient with a support group located geographically nearby the patient and/or a support group including members with whom the patient has a personal and/or professional relationship. Automating the process of associating the patient with a support group reduces the search burden on the patient or caregiver. In some embodiments, the patient may be associated with a support group based upon the patient's pre-existing social networking based relationships (e.g., Facebook friendships), which may

further simplify the process of identifying appropriate members for the support group. Yet another technical effect of the presently disclosed methods and systems is that they automatically send a help request to the support group in response to a determination of the patient's non-compliance with the treatment regimen. Accordingly, the systems and methods provide a relatively simplistic trigger for notifying the support group, which can help minimize the amount of data processing needed to alert the support group. While the foregoing mentions several technical effects associated with the invention, other technical effects will be readily apparent to one of ordinary skill in the art upon a review of this disclosure.

**[0140]** The above description describes various systems and methods for use with a drug delivery device. It should be clear that the system, drug delivery device or methods can further comprise use of a medicament listed below with the caveat that the following list should neither be considered to be all inclusive nor limiting. The medicament 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 medicament. The primary container can be a cartridge or a pre-filled syringe.

**[0141]** For example, the drug delivery device or more specifically the reservoir of the device may be filled with colony stimulating factors, such as granulocyte colony-stimulating factor (G-CSF). Such G-CSF agents include, but are not limited to, Neupogen® (filgrastim) and Neulasta® (pegfilgrastim). In various other embodiments, the drug delivery device may be used with various pharmaceutical products, such as an erythropoiesis stimulating agent (ESA), which may be in a liquid or a lyophilized form. An ESA is any molecule that stimulates erythropoiesis, such as Epo-gen® (epoetin alfa), Aranesp® (darbepoetin alfa), Dynepo® (epoetin delta), Mircera® (methoxy polyethylene glycol-epoetin beta), Hematide®, MRK-2578, INS-22, Retacrit® (epoetin zeta), Neorecormon® (epoetin beta), Silapo® (epoetin zeta), Binocrit® (epoetin alfa), epoetin alfa Hexal, Abseamed® (epoetin alfa), Ratioepo® (epoetin theta), Epo-ratio® (epoetin theta), Biopoin® (epoetin theta), epoetin alfa, epoetin beta, epoetin zeta, epoetin theta, and epoetin delta, as well as the molecules or variants or analogs thereof as disclosed in the following patents or patent applications, each of which is herein incorporated by reference in its entirety: U.S. Pat. Nos. 4,703,008; 5,441,868; 5,547,933; 5,618,698; 5,621,080; 5,756,349; 5,767,078; 5,773,569; 5,955,422; 5,986,047; 6,583,272; 7,084,245; and 7,271,689; and PCT Publication Nos. WO 91/05867; WO 95/05465; WO 96/40772; WO 00/24893; WO 01/81405; and WO 2007/136752.

**[0142]** An ESA can be 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, epoetin alfa, epoetin beta, epoetin delta, epoetin omega, epoetin iota, epoetin zeta, and analogs thereof, pegylated erythropoietin, carbamylated erythropoietin, mimetic peptides (including



EMP1/hematide), and mimetic antibodies. Exemplary erythropoiesis stimulating proteins include erythropoietin, darbepoetin, erythropoietin agonist variants, and peptides or antibodies that bind and activate erythropoietin receptor (and include compounds reported in U.S. Publication Nos. 2003/0215444 and 2006/0040858, the disclosures of each of which is incorporated herein by reference in its entirety) as well as erythropoietin molecules or variants or analogs thereof as disclosed in the following patents or patent applications, which are each herein incorporated by reference in its entirety: U.S. Pat. Nos. 4,703,008; 5,441,868; 5,547,933; 5,618,698; 5,621,080; 5,756,349; 5,767,078; 5,773,569; 5,955,422; 5,830,851; 5,856,298; 5,986,047; 6,030,086; 6,310,078; 6,391,633; 6,583,272; 6,586,398; 6,900,292; 6,750,369; 7,030,226; 7,084,245; and 7,217,689; U.S. Publication Nos. 2002/0155998; 2003/0077753; 2003/0082749; 2003/0143202; 2004/0009902; 2004/0071694; 2004/0091961; 2004/0143857; 2004/0157293; 2004/0175379; 2004/0175824; 2004/0229318; 2004/0248815; 2004/0266690; 2005/0019914; 2005/0026834; 2005/0096461; 2005/0107297; 2005/0107591; 2005/0124045; 2005/0124564; 2005/0137329; 2005/0142642; 2005/0143292; 2005/0153879; 2005/0158822; 2005/0158832; 2005/0170457; 2005/0181359; 2005/0181482; 2005/0192211; 2005/0202538; 2005/0227289; 2005/0244409; 2006/0088906; and 2006/0111279; and PCT Publication Nos. WO 91/05867; WO 95/05465; WO 99/66054; WO 00/24893; WO 01/81405; WO 00/61637; WO 01/36489; WO 02/014356; WO 02/19963; WO 02/20034; WO 02/49673; WO 02/085940; WO 03/029291; WO 2003/055526; WO 2003/084477; WO 2003/094858; WO 2004/002417; WO 2004/002424; WO 2004/009627; WO 2004/024761; WO 2004/033651; WO 2004/035603; WO 2004/043382; WO 2004/101600; WO 2004/101606; WO 2004/101611; WO 2004/106373; WO 2004/018667; WO 2005/001025; WO 2005/001136; WO 2005/021579; WO 2005/025606; WO 2005/032460; WO 2005/051327; WO 2005/063808; WO 2005/063809; WO 2005/070451; WO 2005/081687; WO 2005/084711; WO 2005/103076; WO 2005/100403; WO 2005/092369; WO 2006/50959; WO 2006/02646; and WO 2006/29094.

**[0143]** Examples of other pharmaceutical products for use with the device may include, but are not limited to, antibodies such as Vectibix® (panitumumab), Xgeva™ (denosumab) and Prolia™ (denosumab); other biological agents such as Enbrel® (etanercept, TNF-receptor/Fc fusion protein, TNF blocker), Neulasta® (pegfilgrastim, pegylated filgrastim, pegylated G-CSF, pegylated hu-Met-G-CSF), Neupogen® (filgrastim, G-CSF, hu-MetG-CSF), and Nplate® (romiplostim); small molecule drugs such as Sensipar® (cinacalcet). The device may also be used with a therapeutic antibody, a polypeptide, a protein or other chemical, such as an iron, for example, ferumoxytol, iron dextran, ferric glyconate, and iron sucrose. The pharmaceutical product may be in liquid form, or reconstituted from lyophilized form.

**[0144]** Among particular illustrative proteins are the specific proteins set forth below, including fusions, fragments, analogs, variants or derivatives thereof:

**[0145]** OPGL specific antibodies, peptibodies, and 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, including but not limited

to the antibodies described in PCT Publication No. WO 03/002713, which is incorporated herein in its entirety as to OPGL specific antibodies and antibody related proteins, particularly those having the sequences set forth therein, particularly, but not limited to, those denoted therein: 9H7; 18B2; 2D8; 2E11; 16E1; and 22B3, including the OPGL specific antibodies having either the light chain of SEQ ID NO:2 as set forth therein in FIG. 2 and/or the heavy chain of SEQ ID NO:4, as set forth therein in FIG. 4, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

**[0146]** Myostatin binding proteins, peptibodies, and related proteins, and the like, including myostatin specific peptibodies, particularly those described in U.S. Publication No. 2004/0181033 and PCT Publication No. WO 2004/058988, which are incorporated by reference herein in their entirety particularly in parts pertinent to myostatin specific peptibodies, including but not limited to peptibodies of the mTN8-19 family, including those of SEQ ID NOS:305-351, including TN8-19-1 through TN8-19-40, TN8-19 con1 and TN8-19 con2; peptibodies of the mL2 family of SEQ ID NOS:357-383; the mL15 family of SEQ ID NOS:384-409; the mL17 family of SEQ ID NOS:410-438; the mL20 family of SEQ ID NOS:439-446; the mL21 family of SEQ ID NOS:447-452; the mL24 family of SEQ ID NOS:453-454; and those of SEQ ID NOS:615-631, each of which is individually and specifically incorporated by reference herein in their entirety fully as disclosed in the foregoing publication;

**[0147]** IL-4 receptor specific antibodies, peptibodies, and related proteins, and the like, particularly those that inhibit activities mediated by binding of IL-4 and/or IL-13 to the receptor, including those described in PCT Publication No. WO 2005/047331 or PCT Application No. PCT/US2004/37242 and in U.S. Publication No. 2005/112694, which are incorporated herein by reference in their entirety particularly in parts pertinent to IL-4 receptor specific antibodies, particularly such antibodies as are described therein, particularly, and without limitation, those designated therein: L1H1; L1H2; L1H3; L1H4; L1H5; L1H6; L1H7; L1H8; L1H9; L1H10; L1H11; L2H1; L2H2; L2H3; L2H4; L2H5; L2H6; L2H7; L2H8; L2H9; L2H10; L2H11; L2H12; L2H13; L2H14; L3H1; L4H1; L5H1; L6H1, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

**[0148]** Interleukin 1-receptor 1 ("IL1-R1") specific antibodies, peptibodies, and related proteins, and the like, including but not limited to those described in U.S. Publication No. 2004/097712, which is incorporated herein by reference in its entirety in parts pertinent to IL1-R1 specific binding proteins, monoclonal antibodies in particular, especially, without limitation, those designated therein: 15CA, 26F5, 27F2, 24E12, and 10H7, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the aforementioned publication;

**[0149]** Ang2 specific antibodies, peptibodies, and related proteins, and the like, including but not limited to those described in PCT Publication No. WO 03/057134 and U.S. Publication No. 2003/0229023, each of which is incorporated herein by reference in its entirety particularly in parts pertinent to Ang2 specific antibodies and peptibodies and the like, especially those of sequences described therein and

including but not limited to: L1(N); L1(N) WT; L1(N) 1K WT; 2xL1(N); 2xL1(N) WT; Con4 (N); Con4 (N) 1K WT; 2xCon4 (N) 1K; L1C; L1C 1K; 2xL1C; Con4C; Con4C 1K; 2xCon4C 1K; Con4-L1 (N); Con4-L1C; TN-12-9 (N); C17 (N); TN8-8(N); TN8-14 (N); Con 1 (N), also including anti-Ang 2 antibodies and formulations such as those described in PCT Publication No. WO 2003/030833 which is incorporated herein by reference in its entirety as to the same, particularly Ab526; Ab528; Ab531; Ab533; Ab535; Ab536; Ab537; Ab540; Ab543; Ab544; Ab545; Ab546; A551; Ab553; Ab555; Ab558; Ab559; Ab565; AbF1AbFD; AbFE; AbFJ; AbFK; AbG1D4; AbGC1E8; AbH1C12; AbIA1; AbIF; AbIK; AbIP; and AbLP, in their various permutations as described therein, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

**[0150]** NGF specific antibodies, peptibodies, and related proteins, and the like including, in particular, but not limited to those described in U.S. Publication No. 2005/0074821 and U.S. Pat. No. 6,919,426, which are incorporated herein by reference in their entirety particularly as to NGF-specific antibodies and related proteins in this regard, including in particular, but not limited to, the NGF-specific antibodies therein designated 4D4, 4G6, 6H9, 7H2, 14D10 and 14D11, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

**[0151]** CD22 specific antibodies, peptibodies, and related proteins, and the like, such as those described in U.S. Pat. No. 5,789,554, which is incorporated herein by reference in its entirety as to CD22 specific antibodies and related proteins, 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, for instance, a dimer of a human-mouse monoclonal hLL2 gamma-chain disulfide linked to a human-mouse monoclonal hLL2 kappa-chain, including, but limited to, for example, the human CD22 specific fully humanized antibody in Epratuzumab, CAS registry number 501423-23-0;

**[0152]** IGF-1 receptor specific antibodies, peptibodies, and related proteins, and the like, such as those described in PCT Publication No. WO 06/069202, which is incorporated herein by reference in its entirety as to IGF-1 receptor specific antibodies and related proteins, including but not limited to the IGF-1 specific antibodies therein designated L1H1, L2H2, L3H3, L4H4, L5H5, L6H6, L7H7, L8H8, L9H9, L10H10, L11H11, L12H12, L13H13, L14H14, L15H15, L16H16, L17H17, L18H18, L19H19, L20H20, L21H21, L22H22, L23H23, L24H24, L25H25, L26H26, L27H27, L28H28, L29H29, L30H30, L31H31, L32H32, L33H33, L34H34, L35H35, L36H36, L37H37, L38H38, L39H39, L40H40, L41H41, L42H42, L43H43, L44H44, L45H45, L46H46, L47H47, L48H48, L49H49, L50H50, L51H51, L52H52, and IGF-1R-binding fragments and derivatives thereof, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

**[0153]** Also among non-limiting examples of anti-IGF-1R antibodies for use in the methods and compositions of the present invention are each and all of those described in:

**[0154]** (i) U.S. Publication No. 2006/0040358 (published Feb. 23, 2006), 2005/0008642 (published Jan.

13, 2005), 2004/0228859 (published Nov. 18, 2004), including but not limited to, for instance, antibody 1A (DSMZ Deposit No. DSM ACC 2586), antibody 8 (DSMZ Deposit No. DSM ACC 2589), antibody 23 (DSMZ Deposit No. DSM ACC 2588) and antibody 18 as described therein;

**[0155]** (ii) PCT Publication No. WO 06/138729 (published Dec. 28, 2006) and WO 05/016970 (published Feb. 24, 2005), and Lu et al. (2004), J. Biol. Chem. 279:2856-2865, including but not limited to antibodies 2F8, A12, and IMC-A12 as described therein;

**[0156]** (iii) PCT Publication No. WO 07/012614 (published Feb. 1, 2007), WO 07/000328 (published Jan. 4, 2007), WO 06/013472 (published Feb. 9, 2006), WO 05/058967 (published Jun. 30, 2005), and WO 03/059951 (published Jul. 24, 2003);

**[0157]** (iv) U.S. Publication No. 2005/0084906 (published Apr. 21, 2005), including but not limited to antibody 7C10, chimaeric antibody C7C10, antibody h7C10, antibody 7H2M, chimaeric antibody \*7C10, antibody GM 607, humanized antibody 7C10 version 1, humanized antibody 7C10 version 2, humanized antibody 7C10 version 3, and antibody 7H2HM, as described therein;

**[0158]** (v) U.S. Publication Nos. 2005/0249728 (published Nov. 10, 2005), 2005/0186203 (published Aug. 25, 2005), 2004/0265307 (published Dec. 30, 2004), and 2003/0235582 (published Dec. 25, 2003) and Maloney et al. (2003), Cancer Res. 63:5073-5083, including but not limited to antibody EM164, resurfaced EM164, humanized EM164, huEM164 v1.0, huEM164 v1.1, huEM164 v1.2, and huEM164 v1.3 as described therein;

**[0159]** (vi) U.S. Pat. No. 7,037,498 (issued May 2, 2006), U.S. Publication Nos. 2005/0244408 (published Nov. 30, 2005) and 2004/0086503 (published May 6, 2004), and Cohen, et al. (2005), Clinical Cancer Res. 11:2063-2073, e.g., antibody CP-751,871, including but not limited to each of the antibodies produced by the hybridomas having the ATCC accession numbers PTA-2792, PTA-2788, PTA-2790, PTA-2791, PTA-2789, PTA-2793, and antibodies 2.12.1, 2.13.2, 2.14.3, 3.1.1, 4.9.2, and 4.17.3, as described therein;

**[0160]** (vii) U.S. Publication Nos. 2005/0136063 (published Jun. 23, 2005) and 2004/0018191 (published Jan. 29, 2004), including but not limited to antibody 19D12 and an antibody comprising a heavy chain encoded by a polynucleotide in plasmid 15H12/19D12 HCA ( $\gamma$ 4), deposited at the ATCC under number PTA-5214, and a light chain encoded by a polynucleotide in plasmid 15H12/19D12 LCF ( $\kappa$ ), deposited at the ATCC under number PTA-5220, as described therein; and

**[0161]** (viii) U.S. Publication No. 2004/0202655 (published Oct. 14, 2004), including but not limited to antibodies PINT-6A1, PINT-7A2, PINT-7A4, PINT-7A5, PINT-7A6, PINT-8A1, PINT-9A2, PINT-11A1, PINT-11A2, PINT-11A3, PINT-11A4, PINT-11A5, PINT-11A7, PINT-11A12, PINT-12A1, PINT-12A2, PINT-12A3, PINT-12A4, and PINT-12A5, as described therein; each and all of which are herein incorporated by reference in their entireties, particularly as to the aforementioned antibodies, peptibodies, and related proteins and the like that target IGF-1 receptors;

**[0162]** B-7 related protein 1 specific antibodies, peptibodies, related proteins and the like ("B7RP-1," also is referred to in the literature as B7H2, ICOSL, B7h, and CD275), particularly B7RP-specific fully human monoclonal IgG2 antibodies, particularly fully human IgG2 monoclonal antibody that binds an epitope in the first immunoglobulin-like domain of B7RP-1, especially those that inhibit the interaction of B7RP-1 with its natural receptor, ICOS, on activated T cells in particular, especially, in all of the foregoing regards, those disclosed in U.S. Publication No. 2008/0166352 and PCT Publication No. WO 07/011941, which are incorporated herein by reference in their entireties as to such antibodies and related proteins, including but not limited to antibodies designated therein as follow: 16H (having light chain variable and heavy chain variable sequences SEQ ID NO:1 and SEQ ID NO:7 respectively therein); 5D (having light chain variable and heavy chain variable sequences SEQ ID NO:2 and SEQ ID NO:9 respectively therein); 2H (having light chain variable and heavy chain variable sequences SEQ ID NO:3 and SEQ ID NO:10 respectively therein); 43H (having light chain variable and heavy chain variable sequences SEQ ID NO:6 and SEQ ID NO:14 respectively therein); 41H (having light chain variable and heavy chain variable sequences SEQ ID NO:5 and SEQ ID NO:13 respectively therein); and 15H (having light chain variable and heavy chain variable sequences SEQ ID NO:4 and SEQ ID NO:12 respectively therein), each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication;

**[0163]** IL-15 specific antibodies, peptibodies, and related proteins, and the like, such as, in particular, humanized monoclonal antibodies, particularly antibodies such as those disclosed in U.S. Publication Nos. 2003/0138421; 2003/023586; and 2004/0071702; and U.S. Pat. No. 7,153,507, each of which is incorporated herein by reference in its entirety as to IL-15 specific antibodies and related proteins, including peptibodies, including particularly, for instance, but not limited to, HuMax IL-15 antibodies and related proteins, such as, for instance, 146B7;

**[0164]** IFN gamma specific antibodies, peptibodies, and related proteins and the like, especially human IFN gamma specific antibodies, particularly fully human anti-IFN gamma antibodies, such as, for instance, those described in U.S. Publication No. 2005/0004353, which is incorporated herein by reference in its entirety as to IFN gamma specific antibodies, particularly, for example, the antibodies therein designated 1118; 1118\*; 1119; 1121; and 1121\*. The entire sequences of the heavy and light chains of each of these antibodies, as well as the sequences of their heavy and light chain variable regions and complementarity determining regions, are each individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publication and in Thakur et al. (1999), *Mol. Immunol.* 36:1107-1115. In addition, description of the properties of these antibodies provided in the foregoing publication is also incorporated by reference herein in its entirety. Specific antibodies include those having the heavy chain of SEQ ID NO:17 and the light chain of SEQ ID NO:18; those having the heavy chain variable region of SEQ ID NO:6 and the light chain variable region of SEQ ID NO:8; those having the heavy chain of SEQ ID NO:19 and the light chain of SEQ ID NO:20; those having the heavy chain variable region of SEQ ID NO:10 and the light chain

variable region of SEQ ID NO:12; those having the heavy chain of SEQ ID NO:32 and the light chain of SEQ ID NO:20; those having the heavy chain variable region of SEQ ID NO:30 and the light chain variable region of SEQ ID NO:12; those having the heavy chain sequence of SEQ ID NO:21 and the light chain sequence of SEQ ID NO:22; those having the heavy chain variable region of SEQ ID NO:14 and the light chain variable region of SEQ ID NO:16; those having the heavy chain of SEQ ID NO:21 and the light chain of SEQ ID NO:33; and those having the heavy chain variable region of SEQ ID NO:14 and the light chain variable region of SEQ ID NO:31, as disclosed in the foregoing publication. A specific antibody contemplated is antibody 1119 as disclosed in the foregoing U.S. publication and having a complete heavy chain of SEQ ID NO:17 as disclosed therein and having a complete light chain of SEQ ID NO:18 as disclosed therein;

**[0165]** TALL-1 specific antibodies, peptibodies, and the related proteins, and the like, and other TALL specific binding proteins, such as those described in U.S. Publication Nos. 2003/0195156 and 2006/0135431, each of which is incorporated herein by reference in its entirety as to TALL-1 binding proteins, particularly the molecules of Tables 4 and 5B, each of which is individually and specifically incorporated by reference herein in its entirety fully as disclosed in the foregoing publications;

**[0166]** Parathyroid hormone ("PTH") specific antibodies, peptibodies, and related proteins, and the like, such as those described in U.S. Pat. No. 6,756,480, which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind PTH;

**[0167]** Thrombopoietin receptor ("TPO-R") specific antibodies, peptibodies, and related proteins, and the like, such as those described in U.S. Pat. No. 6,835,809, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind TPO-R;

**[0168]** Hepatocyte growth factor ("HGF") specific antibodies, peptibodies, and related proteins, and the like, including those that target the HGF/SF:cMet axis (HGF/SF: c-Met), such as the fully human monoclonal antibodies that neutralize hepatocyte growth factor/scatter (HGF/SF) described in U.S. Publication No. 2005/0118643 and PCT Publication No. WO 2005/017107, huL2G7 described in U.S. Pat. No. 7,220,410 and OA-5d5 described in U.S. Pat. Nos. 5,686,292 and 6,468,529 and in PCT Publication No. WO 96/38557, each of which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind HGF;

**[0169]** TRAIL-R2 specific antibodies, peptibodies, related proteins and the like, such as those described in U.S. Pat. No. 7,521,048, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind TRAIL-R2;

**[0170]** Activin A specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Publication No. 2009/0234106, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind Activin A;

**[0171]** TGF-beta specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Pat. No. 6,803,453 and U.S. Publication No. 2007/0110747, each of which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind TGF-beta;

**[0172]** Amyloid-beta protein specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in PCT Publication No. WO 2006/081171, which is herein incorporated by reference in its entirety, particularly in parts pertinent to proteins that bind amyloid-beta proteins. One antibody contemplated is an antibody having a heavy chain variable region comprising SEQ ID NO:8 and a light chain variable region having SEQ ID NO:6 as disclosed in the foregoing publication;

**[0173]** c-Kit specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Publication No. 2007/0253951, which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind c-Kit and/or other stem cell factor receptors;

**[0174]** OX40L specific antibodies, peptibodies, related proteins, and the like, including but not limited to those described in U.S. Publication No. 2006/0002929, which is incorporated herein by reference in its entirety, particularly in parts pertinent to proteins that bind OX40L and/or other ligands of the OX40 receptor; and

**[0175]** Other exemplary proteins, including Activase® (alteplase, tPA); Aranesp® (darbepoetin alfa); Epogen® (epoetin alfa, or erythropoietin); GLP-1, Avonex® (interferon beta-1a); Bexxar® (tositumomab, anti-CD22 monoclonal antibody); Betaseron® (interferon-beta); Campath® (alemtuzumab, anti-CD52 monoclonal antibody); Dynepo® (epoetin delta); Velcade® (bortezomib); MLN0002 (anti- $\alpha$ 4 $\beta$ 7 mAb); MLN1202 (anti-CCR2 chemokine receptor mAb); Enbrel® (etanercept, TNF-receptor/Fc fusion protein, TNF blocker); Eprex® (epoetin alfa); Erbitux® (cetuximab, anti-EGFR/HER1/c-ErbB-1); Genotropin® (somatropin, Human Growth Hormone); Herceptin® (trastuzumab, anti-HER2/neu (erbB2) receptor mAb); Humatrope® (somatropin, Human Growth Hormone); Humira® (adalimumab); 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™ (lymphotoxin 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); Neulasta® (pegylated filgrastim, pegylated G-CSF, pegylated hu-Met-G-CSF); Neupogen® (filgrastim, G-CSF, hu-Met-G-CSF); Orthoclone OKT3® (muromonab-CD3, anti-CD3 monoclonal antibody); Procrit® (epoetin alfa); Remicade® (infliximab, anti-TNF $\alpha$  monoclonal antibody); Reopro® (abciximab, anti-GP IIb/IIIa receptor monoclonal antibody); Actemra® (anti-IL6 Receptor mAb); Avastin® (bevacizumab), HuMax-CD4 (zanolimumab); Rituxan® (rituximab, anti-CD20 mAb); Tarceva® (erlotinib); Roferon-A® (interferon alfa-2a); Simulect® (basiliximab); Prexige® (lumiracoxib); Synagis® (palivizumab); 146B7-CHO (anti-IL15 antibody, see U.S. Pat. No. 7,153,507); Tysabri® (natalizumab, anti-

$\alpha$ 4integrin mAb); Valortim® (MDX-1303, anti-B. anthracis protective antigen mAb); ABthrax™; Vectibix® (panitumumab); Xolair® (omalizumab); ETI211 (anti-MRSA mAb); IL-1 trap (the Fc portion of human IgG1 and the extracellular domains of both IL-1 receptor components (the Type I receptor and receptor accessory protein)); VEGF trap (Ig domains of VEGFR1 fused to IgG1 Fc); Zenapax® (daclizumab); Zenapax® (daclizumab, anti-IL-2R $\alpha$  mAb); Zevalin® (ibritumomab tiuxetan); Zetia® (ezetimibe); Orencia® (atacept, TACI-Ig); anti-CD80 monoclonal antibody (galiximab); anti-CD23 mAb (lumiliximab); BR2-Fc (huBR3/huFc fusion protein, soluble BAFF antagonist); CNTO 148 (golimumab, anti-TNF $\alpha$  mAb); HGS-ETR1 (mapatumumab; human anti-TRAIL Receptor-1 mAb); HuMax-CD20 (ocrelizumab, anti-CD20 human mAb); HuMax-EGFR (zalutumumab); M200 (volociximab, anti- $\alpha$ 5 $\beta$ 1 integrin mAb); MDX-010 (ipilimumab, anti-CTLA-4 mAb and VEGFR-1 (IMC-18F1); anti-BR3 mAb; anti-C. difficile Toxin A and Toxin B C mAbs MDX-066 (CDA-1) and MDX-1388); anti-CD22 dsFv-PE38 conjugates (CAT-3888 and CAT-8015); anti-CD25 mAb (HuMax-TAC); anti-CD3 mAb (NI-0401); adecatumumab; anti-CD30 mAb (MDX-060); MDX-1333 (anti-IFNAR); anti-CD38 mAb (HuMax CD38); anti-CD4OL mAb; anti-Cripto mAb; anti-CTGF Idiopathic Pulmonary Fibrosis Phase I Fibrogen (FG-3019); anti-CTLA4 mAb; anti-eotaxin1 mAb (CAT-213); anti-FGF8 mAb; anti-ganglioside GD2 mAb; anti-ganglioside GM2 mAb; anti-GDF-8 human mAb (MYO-029); anti-GM-CSF Receptor mAb (CAM-3001); anti-HepC mAb (HuMax HepC); anti-IFN $\alpha$  mAb (MEDI-545, MDX-1103); 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); anti-LLY antibody; BMS-66513; anti-Mannose Receptor/hCG $\beta$  mAb (MDX-1307); anti-mesothelin dsFv-PE38 conjugate (CAT-5001); anti-PD1mAb (MDX-1106 (ONO-4538)); anti-PDGFR $\alpha$  antibody (IMC-3G3); anti-TGF $\beta$  mAb (GC-1008); anti-TRAIL Receptor-2 human mAb (HGS-ETR2); anti-TWEAK mAb; anti-VEGFR/Flt-1 mAb; anti-ZP3 mAb (HuMax-ZP3); NVS Antibody #1; and NVS Antibody #2.

**[0176]** Also included can be a sclerostin antibody, such as but not limited to romosozumab, blosozumab, or BPS 804 (Novartis). Further included can be therapeutics such as rilotumumab, bixalomer, trebananib, ganitumab, conatumumab, motesanib diphosphate, brodalumab, vidupirant, panitumumab, denosumab, NPLATE, PROLIA, VECTIBIX or XGEVA. Additionally, included in the device can be a monoclonal antibody (IgG) that binds human Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9), e.g. U.S. Pat. No. 8,030,547, U.S. Publication No. 2013/0064825, WO2008/057457, WO2008/057458, WO2008/057459, WO2008/063382, WO2008/133647, WO2009/100297, WO2009/100318, WO2011/037791, WO2011/053759, WO2011/053783, WO2008/125623, WO2011/072263, WO2009/055783, WO2012/0544438, WO2010/029513, WO2011/111007, WO2010/077854, WO2012/088313, WO2012/101251, WO2012/101252, WO2012/101253, WO2012/109530, and WO2001/031007.

**[0177]** Also included can be talimogene laherparepvec or another oncolytic HSV for the treatment of melanoma or other cancers. Examples of oncolytic HSV include, but are

not limited to talimogene laherparepvec (U.S. Pat. Nos. 7,223,593 and 7,537,924); OncoVEXGALV/CD (U.S. Pat. No. 7,981,669); OrienX010 (Lei et al. (2013), World J. Gastroenterol., 19:5138-5143); G207, 1716; NV1020; NV12023; NV1034 and NV1042 (Vargehes et al. (2002), Cancer Gene Ther., 9(12):967-978).

**[0178]** Also included are TIMPs. TIMPs are endogenous tissue inhibitors of metalloproteinases (TIMPs) and are important in many natural processes. TIMP-3 is expressed by various cells or and is present in the extracellular matrix; it inhibits all the major cartilage-degrading metalloproteinases, and may play a role in many degradative diseases of connective tissue, including rheumatoid arthritis and osteoarthritis, as well as in cancer and cardiovascular conditions. The amino acid sequence of TIMP-3, and the nucleic acid sequence of a DNA that encodes TIMP-3, are disclosed in U.S. Pat. No. 6,562,596, issued May 13, 2003, the disclosure of which is incorporated by reference herein. Description of TIMP mutations can be found in U.S. Publication No. 2014/0274874 and PCT Publication No. WO 2014/152012.

**[0179]** Also included are antagonistic antibodies for human calcitonin gene-related peptide (CGRP) receptor and bispecific antibody molecule that target the CGRP receptor and other headache targets. Further information concerning these molecules can be found in PCT Application No. WO 2010/075238.

**[0180]** Additionally, a bispecific T cell engager antibody (BiTe), e.g. Blinotumomab can be used in the device. Alternatively, included can be an APJ large molecule agonist e.g., apelin or analogues thereof in the device. Information relating to such molecules can be found in PCT Publication No. WO 2014/099984.

**[0181]** In certain embodiments, the medicament comprises a therapeutically effective amount of an anti-thymic stromal lymphopoietin (TSLP) or TSLP receptor antibody. Examples of anti-TSLP antibodies that may be used in such embodiments include, but are not limited to, those described in U.S. Pat. Nos. 7,982,016, and 8,232,372, and U.S. Publication No. 2009/0186022. Examples of anti-TSLP receptor antibodies include, but are not limited to, those described in U.S. Pat. No. 8,101,182. In particularly preferred embodiments, the medicament comprises a therapeutically effective amount of the anti-TSLP antibody designated as AS within U.S. Pat. No. 7,982,016.

**[0182]** It should be noted that the configurations of the various embodiments of the drug delivery devices and drug delivery systems described herein are illustrative only. Although only a few embodiments of the of the drug delivery devices and drug delivery systems have been described in detail in this disclosure, those skilled in the art who review this disclosure will readily appreciate that many modifications are possible (e.g., variations in sizes, dimensions, structures, shapes and proportions of the various elements, values of parameters, mounting arrangements, use of materials, orientations, etc.) without materially departing from the novel teachings and advantages of the subject matter of this disclosure. For example, any combination of one or more of the sensors and sensor systems described herein may be incorporated into one or more of the drug delivery systems and drug delivery devices described herein. Also, the order or sequence of any process or method steps described herein may be varied or re-sequenced, in any combination, according to alternative embodiments. Fur-

thermore, any combination of one or more of the elements of one or more of the claims set forth at the end of this disclosure is possible.

**[0183]** Although the preceding text sets forth a detailed description of different embodiments of the invention, it should be understood that the legal scope of the invention is defined by the words of the claims set forth at the end of this patent. The detailed description is to be construed as exemplary only and does not describe every possible embodiment of the invention because describing every possible embodiment would be impractical, if not impossible. 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.

**[0184]** It should also be understood that, unless a term is expressly defined in this patent using the sentence "As used herein, the term '\_\_\_\_\_' is hereby defined to mean . . ." or a similar sentence, there is no intent to limit the meaning of that term, either expressly or by implication, beyond its plain or ordinary meaning, and such term should not be interpreted to be limited in scope based on any statement made in any section of this patent (other than the language of the claims). To the extent that any term recited in the claims at the end of this patent is referred to in this patent in a manner consistent with a single meaning, that is done for sake of clarity only so as to not confuse the reader, and it is not intended that such claim term be limited, by implication or otherwise, to that single meaning. Finally, unless a claim element is defined by reciting the word "means" and a function without the recital of any structure, it is not intended that the scope of any claim element be interpreted based on the application of 35 U.S.C. §112, sixth paragraph.

1. A social networking based method of providing a patient with support, the method comprising:
  - associating the patient with at least one support group;
  - receiving data representative of at least one of a condition or an operational state of a drug delivery device associated with the patient;
  - determining if the patient is compliant with a treatment regimen based on the condition or the operational state of the drug delivery device; and
  - in response to a determination that the patient is not compliant with the treatment regimen, transmitting a communication to the at least one support group requesting the at least one support group to at least counsel the patient about the treatment regimen.
2. The social networking based method of claim 1, wherein the communication to the at least one support group requests the at least one support group to encourage the patient to comply with the treatment regimen.
3. The social networking based method of claim 1, comprising receiving data representative of a geographic location of the patient or the drug delivery device.
4. The social networking based method of claim 3, wherein associating the patient with the at least one support group comprises selecting at least one support group near the geographic location of the patient or the drug delivery device.
5. The social networking based method of claim 1, wherein associating the patient with the at least one support group comprises receiving a selection by the patient indicating the at least one support group.

6. The social networking based method of claim 1, the at least one support group including at least one of a healthcare provider, a caregiver, a family member, a friend, an individual using a similar drug delivery device as the patient, or an individual having a similar medical condition as the patient.

7. The social networking based method of claim 1, wherein the at least one support group is connected through a social networking service.

8. The social networking based method of claim 1, comprising transmitting a communication to a mobile computing device associated with the patient in response to input from the at least one support group, the communication including a message encouraging the patient to comply with the treatment regimen.

9. The social networking based method of claim 1, wherein the data representative of at least one of the condition or an operational state of the drug delivery device comprises sensor data collected from one or more sensors onboard the drug delivery device.

10. The social networking based method of claim 9, wherein determining if the patient is compliant with the treatment regimen comprises determining, based on the sensor data, if a needle shield of the drug delivery device has been moved relative to a delivery cannula and if a plunger of the drug delivery device has completed a delivery stroke.

11. The social networking based method of claim 9, wherein determining if the patient is compliant with the treatment regimen further comprises determining, based on the sensor data, if an actuator has been used to trigger the drug delivery device.

12. The social networking based method of claim 9, wherein determining if the patient is compliant with the treatment regimen comprises determining, based on the sensor data, an amount of medicament remaining in a reservoir of the drug delivery device.

13. The social networking based method of claim 1, comprising transmitting a communication to the at least one support group requesting the at least one support group to remind the patient of a forthcoming action required by the treatment regimen.

14. The social networking based method of claim 1, comprising:

- receiving a request for support from the patient;
- in response to the request for support, transmitting a communication to the at least one support group requesting the at least one support group to address the request for support by contacting the patient.

15. The social networking based method of claim 1, comprising transmitting a communication to the at least one support group requesting the at least one support group to actively intervene by at least meeting with the patient in-person to ensure the patient complies with the treatment regimen.

16. A support system for a patient, the system comprising: a drug delivery system comprising:

- a reservoir;
- a delivery cannula having a proximal end in fluid communication with the reservoir and a distal end to be received within the patient;
- one or more sensors; and
- a first communication module configured to transmit a report representative of at least one of a condition or an operational state of the drug delivery device; and

an external computing device comprising:

- a second communication module configured to receive the report;

- a processor;

- a memory coupled to the processor and configured to store non-transitory, computer-executable instructions that, when executed by the processor, cause the processor to:

- associate the patient with the at least one support group;

- store, in the memory, a predefined criteria for determining compliance with a treatment regimen;

- compare the report with the predefined criteria to determine if the patient is compliant with the treatment regimen; and

- in response to a determination that the patient is not compliant with the treatment regimen, control the second communication module to transmit a communication to the at least one support group requesting the at least one support group to at least counsel the patient about the treatment regimen.

17. The system of claim 16, wherein the communication to the at least one support group requests the at least one support group to encourage the patient to comply with the treatment regimen.

18. The system of claim 16, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to receive data representative of a geographic location of the patient.

19. The system of claim 18, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to associate the patient with the at least one support group by selecting at least one support group near the geographic location of the patient.

20. The system of claim 16, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to associate the patient with the at least one support group in accordance with a selection by the patient indicating the at least one support group.

21. The system of claim 16, the at least one support group including at least one of a healthcare provider, a caregiver, a family member, a friend, an individual using a similar drug delivery device as the patient, or an individual having a similar medical condition as the patient.

22. The system of claim 15, wherein the at least one support group is connected through a social networking service.

23. The system of claim 16, the drug delivery system comprising a mobile computing device associated with the patient, wherein the mobile computing device includes the first communication module and a display.

24. The system of claim 23, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to control the second communication module to transmit a communication to the mobile computing device in response to input from the at least one support group, the communi-

cation including a message to be displayed on the display of the mobile computing device and encouraging the patient to comply with the treatment regimen.

**25.** The system of claim **16**, the drug delivery system comprising a drug delivery device, the drug delivery device including:

- a housing containing the reservoir and the delivery cannula;
- a needle shield moveable relative to the distal end of the delivery cannula;
- a plunger moveable through the reservoir to discharge a medicament from the reservoir;
- an actuator configured to trigger the drug delivery device; and
- the one or more sensors including at least one of: a first sensor configured to determine if the needle shield has been moved relative to the distal end of the delivery cannula, a second sensor configured to detect movement of the plunger, or a third sensor configured to detect movement of the actuator.

**26.** The system of claim **16**, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to control the second communication module to transmit a communication to the at least one support group requesting the at least one support group to remind the patient of a forthcoming action required by the treatment regimen.

**27.** The system of claim **16**, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to:

- receive a request for support from the patient; and
- in response to the request for support, transmit a communication to the at least one support group requesting the at least one support group to address the request for support by contacting the patient.

**28.** The system of claim **16**, wherein the non-transitory, computer-executable instructions stored in the memory of the external computing device include instructions that, when executed by the processor, cause the processor to control the second communication module to transmit a communication to the at least one support group requesting the at least one support group to actively intervene by at least meeting with the patient in-person to ensure the patient complies with the treatment regimen.

**29.** A non-transitory, computer-readable storage medium having computer-executable instructions that, when executed at one or more processors of a support system for a patient, cause the one or more processors to:

- associate the patient with at least one support group;
- receive data representative of at least one of a condition or an operational state of a drug delivery device associated with the patient;
- determine if the patient is compliant with a treatment regimen based on the condition or the operational state of the drug delivery device; and
- in response to a determination that the patient is not compliant with the treatment regimen, transmit a communication to the at least one support group requesting the at least one support group to at least counsel the patient about the treatment regimen.

**30.** The non-transitory, computer-readable storage medium of claim **29**, wherein the communication to the at

least one support group requests the at least one support group to encourage the patient to comply with the treatment regimen.

**31.** The non-transitory, computer-readable storage medium of claim **29**, wherein the instructions, when executed, cause the one or more processors to receive data representative of a geographic location of the patient or the drug delivery device.

**32.** The non-transitory, computer-readable storage medium of claim **29**, wherein the instructions, when executed, cause the one or more processors to associate the patient with the at least one support group comprising selecting at least one support group near the geographic location of the patient or the drug delivery device.

**33.** The non-transitory, computer-readable storage medium of claim **29**, wherein the instructions, when executed, cause the one or more processors to associate the patient with the at least one support group comprising receiving a selection by the patient indicating the at least one support group.

**34.** The non-transitory, computer-readable storage medium of claim **29**, the at least one support group including at least one of a healthcare provider, a caregiver, a family member, a friend, an individual using a similar drug delivery device as the patient, or an individual having a similar medical condition as the patient.

**35.** The non-transitory, computer-readable storage medium of claim **29**, wherein the at least one support group is connected through a social networking service.

**36.** The non-transitory, computer-readable storage medium of claim **29**, wherein the instructions, when executed, cause the one or more processors to transmit a communication to a mobile computing device associated with the patient in response to input from the at least one support group, the communication including a message encouraging the patient to comply with the treatment regimen.

**37.** The non-transitory, computer-readable storage medium of claim **29**, wherein the data representative of at least one of the condition or an operational state of the drug delivery device comprises sensor data collected from one or more sensors onboard the drug delivery device.

**38.** The non-transitory, computer-readable storage medium of claim **37**, wherein the instructions, when executed, cause the one or more processors to determine if the patient is compliant with the treatment regimen comprises determining, based on the sensor data, if a needle shield of the drug delivery device has been moved relative to a delivery cannula and if a plunger of the drug delivery device has completed a delivery stroke.

**39.** The non-transitory, computer-readable storage medium of claim **37**, wherein the instructions, when executed, cause the one or more processors to determine if the patient is compliant with the treatment regimen further comprises determining, based on the sensor data, if an actuator has been used to trigger the drug delivery device.

**40.** The non-transitory, computer-readable storage medium of claim **37**, wherein the instructions, when executed, cause the one or more processors to determine if the patient is compliant with the treatment regimen comprises determining, based on the sensor data, an amount of medicament remaining in a reservoir of the drug delivery device.

41. The non-transitory, computer-readable storage medium of claim 29, wherein the instructions, when executed, cause the one or more processors to transmit a communication to the at least one support group requesting the at least one support group to remind the patient of a forthcoming action required by the treatment regimen.

42. The non-transitory, computer-readable storage medium of claim 29, wherein the instructions, when executed, cause the one or more processors to:

receive a request for support from the patient; and  
in response to the request for support, transmit a communication to the at least one support group requesting the at least one support group to address the request for support by contacting the patient.

43. The non-transitory, computer-readable storage medium of claim 29, wherein the instructions, when executed, cause the one or more processors to transmit a communication to the at least one support group requesting the at least one support group to actively intervene by at least meeting with the patient in-person to ensure the patient complies with the treatment regimen.

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