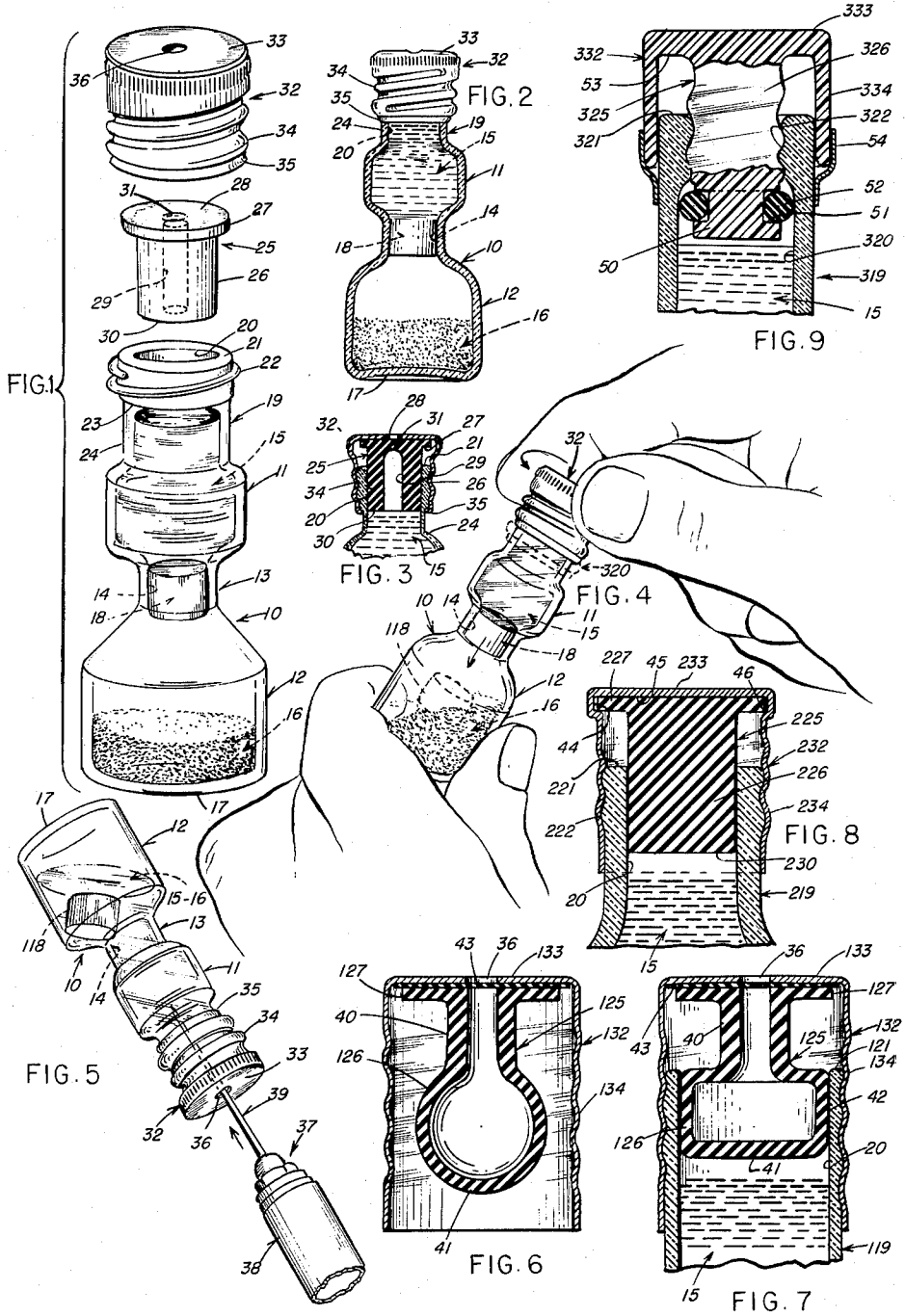
Aug. 3, 1965 E. H. WILBURN 3,198,194

ADMIXING STORAGE CONTAINER WITH MEANS PREVENTING INADVERTENT REMOVAL OF CLOSURE MEANS

Filed May 13, 1963 4 Sheets-Sheet 1



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ADMIXING STORAGE CONTAINER WITH MEANS PREVENTING INADVERTENT REMOVAL OF CLOSURE MEANS
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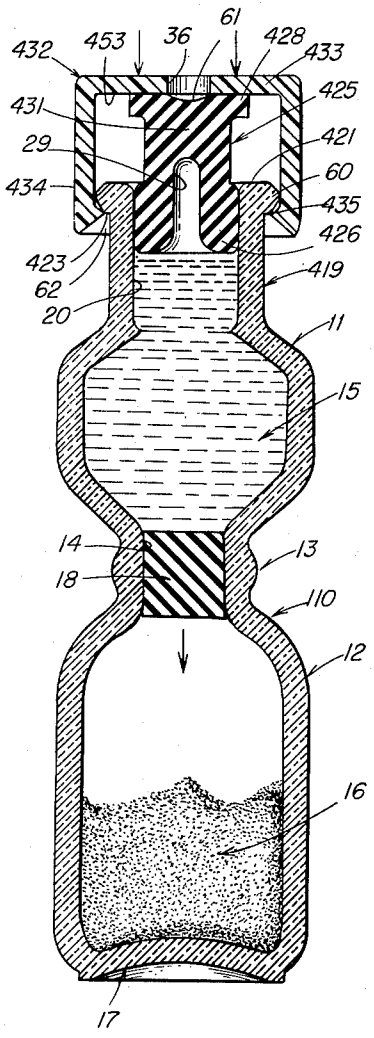
FIG. 10



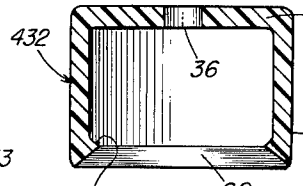


FIG. 11

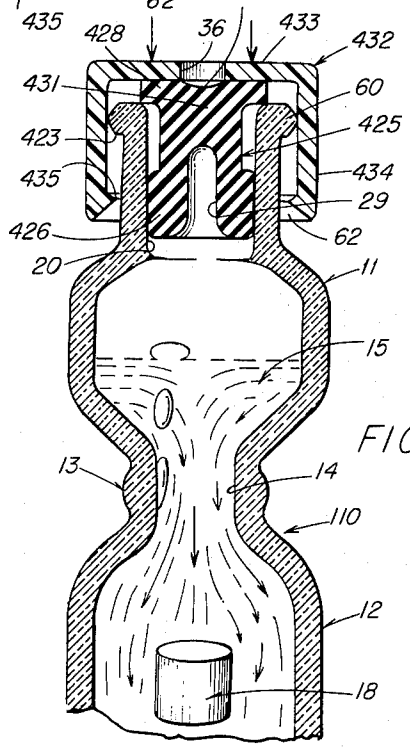


FIG. 12

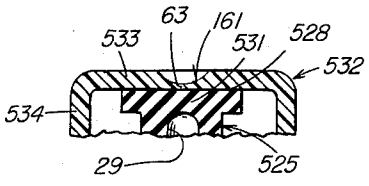


FIG. 13

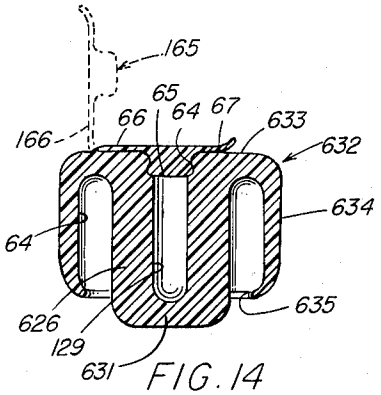


FIG. 14

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ADMIXING STORAGE CONTAINER WITH MEANS PREVENTING INADVERTENT REMOVAL OF CLOSURE MEANS

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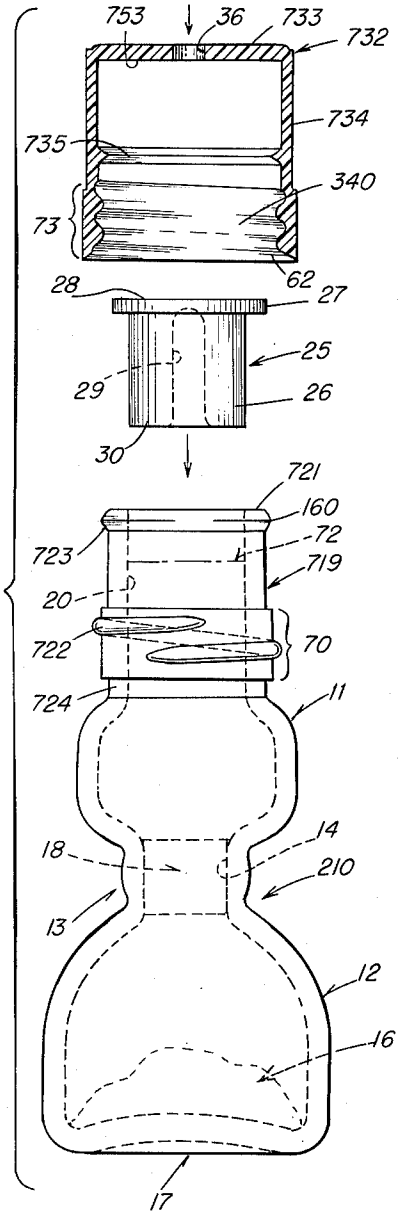

FIG. 15

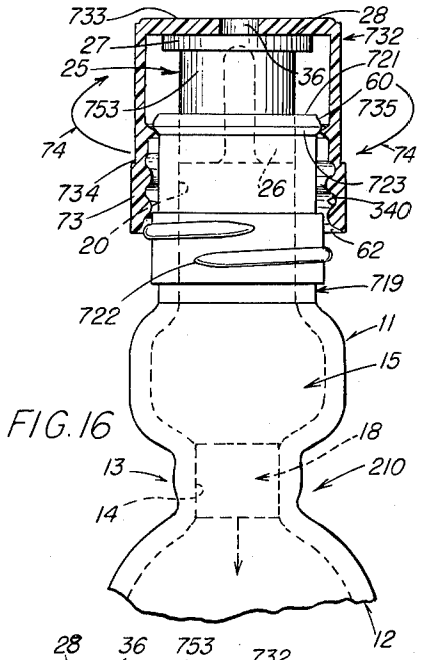

FIG. 16

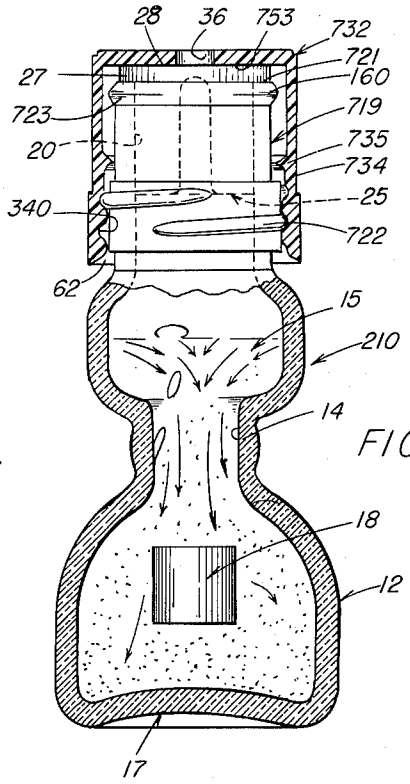

FIG. 17

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ADMIXING STORAGE CONTAINER WITH MEANS PREVENTING INADVERTENT REMOVAL OF CLOSURE MEANS

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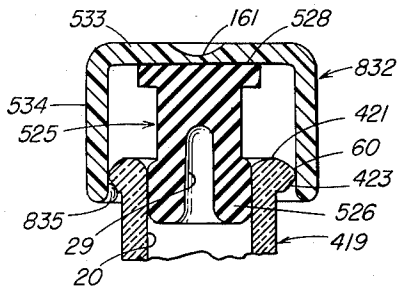

FIG. 18

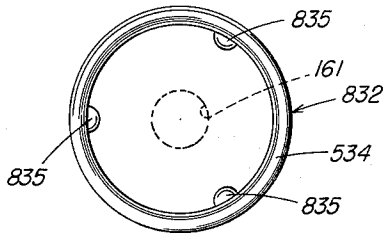

FIG. 19

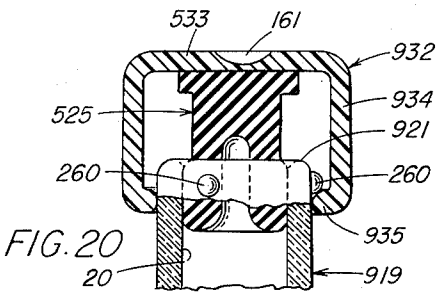

FIG. 20

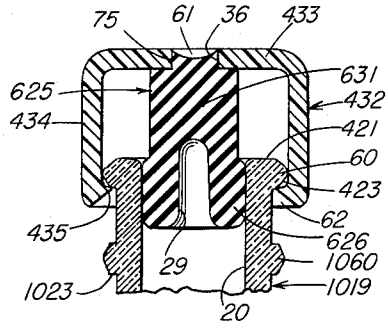

FIG. 21

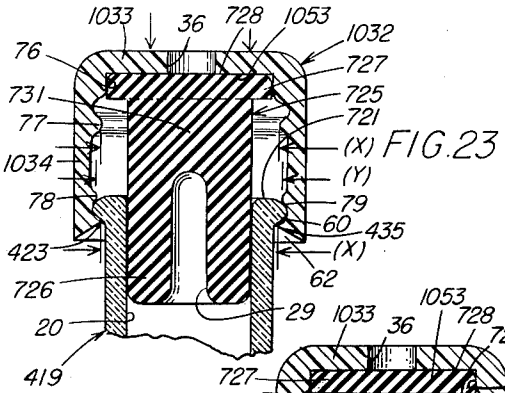

FIG. 23

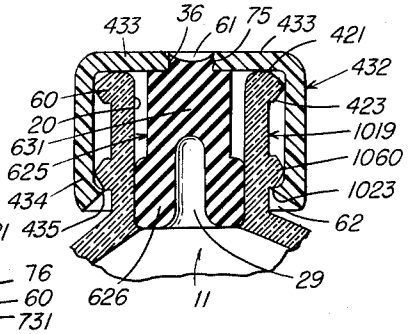

FIG. 22

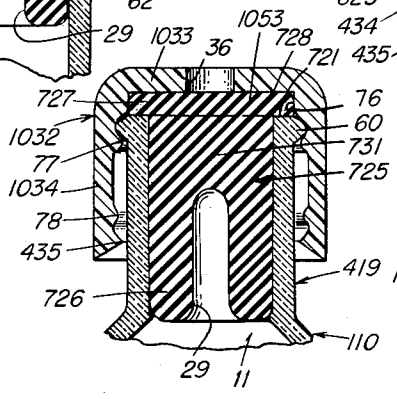

FIG. 24

United States Patent Office 3,198,194 Patented Aug. 3, 1965

3,198,194

ADMIXING STORAGE CONTAINER WITH MEANS PREVENTING INADVERTENT REMOVAL OF CLOSURE MEANS

Edgar H. Wilburn, Rutherford, N.J., assignor to The Upjohn Company, Kalamazoo, Mich.

Filed May 13, 1963, Ser. No. 282,528
2 Claims. (Cl. 128—272)

The present application is a continuation-in-part of application Serial No. 189,005, filed April 20, 1962, now abandoned.

The present invention relates to vials or containers for segregated storage in a pair of separated chambers thereof of different ingredients of solutions and liquid mixtures, such devices being provided with means for bringing the ingredients together at will for admixing them. This invention is an improvement upon the admixing vial described in the Lockhart United States Patent No. 2,610,628 of September 16, 1952.

While admixing storage containers of the type described and claimed in the identified Lockhart patent are efficient for their intended purposes, the piston plug of each which effects "firing" thereof to bring the segregated ingredients together may be difficult or uncomfortable for some to operate, particularly if the thrust post is of small lateral dimension. Also, it may be desirable that some protective means be provided to prevent accidental admixing operation of the device or unintended displacement or knock out of the piston plug during storage and handling. Certain services for which such a device may be employed to advantage also may require or encourage use of captive means for associating the piston plug with the protective means, particularly when the latter is removable and one may require removal of the admixed contents from the container mouth by pouring. Many forms of such admixing storage containers are of capacities as to provide plural-dosage quantities of parenteral liquid mixtures from which are successively drawn off loads for hypodermic syringes, such as by piercing its closure each time with the needle of each syringe and by suction created upon retraction of the piston assembly of the syringe. In the latter case it is important to assure cleanliness of such portions of the container closures which are contacted by the syringe needles, as by eliminating pockets or recesses in which fouling matter can be irremovably collected or from which it could not be easily cleansed by wiping with a swab saturated with cleaning or sterilizing liquid. These and other desirable features are effectively supplied by embodiments of the present invention.

An object of this invention is to provide such an admixing storage container in a certain desirable structural form. The tubular container body thereof has a pair of chamber-defining top and bottom end sections and an intervening mid-section. The mid-section is of a structure defining separating partition means between the top and bottom chambers and it has an intercommunicating passage extending therethrough of appreciably less cross-sectional area than the portion of the bottom chamber thereadjacent, with this passage defining a gate plug seat. An elastic gate plug of suitable material, such as a rubber-like compound, is provided which has a dimension less than that of the adjacent bottom chamber portion so that when expelled from the intercommunicating passage seat it will be freely receptive into the bottom chamber without interfering with flow of liquid through the intercommunicating passage. The elastic gate plug is of a cross-sectional dimension greater than that of the partition seat and it is slidably fitted in constricted condition within the latter whereby it temporarily isolates the top and bottom chambers with a liquid ingredient of an ultimate admixture housed in the top chamber and another material miscible therewith to complete the admixture housed in the bottom chamber. This gate plug is pressure-expellable down from out of its seat into the enlarged adjacent top portion of the bottom chamber for intercommunicating the chambers.

In accordance with the present invention, closure means are provided for the top chamber which includes a tubular loading extension, such as an elongated neck, having an elongated bore terminating in a mouth circumscribed by an annular lip. The bore of the tubular loading extension is of a cross-sectional size throughout its length greater than that of the gate plug so that the latter may be freely inserted down therethrough into the gate plug seat after one of the admixture ingredients, which may be a liquid component or a dissolvable mass of soluble particulate solids and herein termed "miscible material," has been loaded down through the neck bore and the latter into the bottom chamber. The closure means comprises, in addition to the tubular extension, a piston plug and cap assembly including piston plug means having a depending piston section at least provided with an elastic annular zone of greater diameter than a transverse section of the tubular extension bore and slidably fitted in constricted condition within the latter while in an outward initial position preparatory to axially inward translation. In this initial position the elastic annular zone of the piston section has a fluid-tight fit with the transverse section of the tubular extension bore in which it is slidably fitted in constricted condition and this fluid-tight fit is maintained for piston action during axial inward translation of the piston section of the piston plug means. With the piston section in this initial position a top portion of the piston plug means projects an appreciable distance beyond the lip of the lipped top portion of the tubular extension to allow the axially inward translation of the piston section in the bore of the latter through a predetermined distance of thrust.

An amount of the other admixture ingredient, in the form of a liquid, is housed in the top chamber. The amount of this liquid preferably is greater than a predetermined cubic capacity of the top chamber to which it may be reduced by the inward translation of the piston section in the bore, so as to assure that the gate plug will be expelled into the bottom chamber by piston plug-created hydraulic pressure.

The piston plug and cap assembly also includes cap means covering the projecting portion of the piston plug when the cap is in an initial outward mounted position. The cap means has a transverse top wall and a cylindrical skirt depending therefrom with the skirt having a bottom annular zone lapping the lipped top portion of the tubular extension in the initial outward position of the piston plug means. The tubular extension and the piston plug and cap assembly may have in certain forms of the device interengaged mating screw threads for forward screw advance of the assembly upon forward rotation of the cap means to translate the piston section axially inward for hydraulic expulsion of the gate plug from its seat into the bottom chamber. The interengaged mating screw threads may provide desired captive means for the piston plug and cap assembly, and this may be supplemented by other captive means which in some forms may be relied on solely for this function.

The tubular extension may have its threads arranged externally thereof below the lip with the cap skirt carrying the mating threads internally thereof. In such case the piston plug means and the cap means of the piston plug and cap assembly may either be made integral, such as by a single molding operation, or as separate units anchored together after formation. Further, the piston plug and cap may be separately produced and after insertion of

the piston section of the former into the bore of the tubular extension to its initial position the cap may then be threadably applied to the tubular extension protectively to cover the projecting top portion of the piston plug. Alternatively, the bore of the tubular extension may have an internally-threaded section in the vicinity of the lip and the piston plug means may carry the mating threads on its piston section. In the latter case the piston plug means should be rotatable by the cap means, such as by being made integral therewith or, if formed as separate units, these units should be so anchored together that the piston plug means will be rotatable by the cap means. When the piston section carries male threads mated with female threads within the tubular extension bore the required fluid-tight fit therebetween may be attained by forming either the tubular extension or the piston section, or both, of material having some elasticity, such as a suitable plastic, or the piston section may be formed of a rubber compound while the tubular extension is molded from glass or rigid plastic. A loose fit may be provided between screw threads on the piston section and in the tubular extension bore if below the threads in the bore the latter is provided with a cylindrical section and the lower end of the piston section below its threads is fitted with suitable gasketing means, such as an elastic ring, which will wipe axially along this cylindrical bore section, either with or without rotation, as the threaded piston section is rotated forward by the cap.

Another object of the invention is to provide in embodiments of the invention effective gasketing means provided by a part of the piston plug and cap assembly which, after the latter is screwed in to "fire" the device, will tightly close the container mouth effectively against any tendency to leak even though the liquid contents are housed under elevated pressure.

An additional object of the present invention is to provide in embodiments thereof the captive means to secure the cap and piston plug assembly to the container in the form of an external and downwardly facing stop shoulder on the tubular loading extension below its lip, with the cap skirt being provided with internal stop means engaged inward beyond the shoulder so as effectively to retain the cap in its outward mounted position and the covered piston plug within the container mouth, while permitting inward advance either by rotational screwing or non-rotary thrust of the cap to cause the piston plug to develop the required hydraulic pressure for gate plug expulsion. Either the stop shoulder or the stop means may be in the form of one or more localized projections or nibs with the other thereof in the form of an annular rib. In any event the tubular extension or neck below the shoulder is of an axial length at least equal to the thrust distance, with the stop within the cap skirt located radially outward of the axis of the neck a distance less than the maximum radial distance of the stop on the neck from the axis of the latter. In any event, one or the other of these stops, or of the structures on which they are mounted, should be elastic to permit sufficient give allowing the skirt stop to be snapped down over the neck stop.

Effectively, this stop shoulder may be provided as an annular abutment on the tubular loading extension or neck which faces downwardly and with the cooperative stop means being carried by the cap skirt in the form of an internal constriction or annular bead engaged down over the shoulder. This internal stop-defining constriction or annular bead may be located within the depending cap skirt at a point intermediate the transverse top of the cap and the bottom edge of the skirt, to provide an annular zone below this stop means which intervenes the latter and the skirt bottom edge. The internal stop-defining constriction or bead alternatively may be provided as a constriction of the bottom edge of the cap skirt. When the cap is provided with either form of captive means it

may be mounted upon the tubular loading extension or container neck merely by telescopic engagement for axially slidable translation without rotation, or the threaded engagement may be provided whereby internal screw threads in the cap skirit are mated with external screw threads on the container neck and the cap is rotated in a forward direction to attain the screw-threaded advance for causing the axial forward translation of the cap. The cap may be formed of readily malleable metallic material, such as aluminum, and the constriction of the bottom edge of its skirt may be produced by conventional spinning. Alternatively, the cap may be molded from plastic with the bottom edge of its skirt being flexible to permit the molding of this bottom edge in constricted form while permitting ready removal of a mold core pin which may be employed in the molding of such constriction.

The cap, whether formed of readily malleable metal or elastic plastic, may have the bottom annular zone of its skirt below the internal captive bead in the latter utilized for providing the internal screw threads to be engaged with external screw threads on the container neck. When of malleable metal the cap skirt may have an annular channel rolled into its outer surface at an intermediate point to provide the internal annular stop bead, and a similar rolling operation may define below the latter the internal screw threads. When the cap is molded from elastic plastic, such as flexible polyethylene, the internal annular stop bead and the internal screw threads therebelow may be defined by the molding operation with a suitable contoured core pin, the elasticity of the cap material permitting ready stripping of the shaped cap skirt from the latter. With either type of cap the stop means on the container neck may be an annular external bead at its lip of an outer diameter slightly larger than the internal diameter of interior and intermediate cap skirt bead. The external screw threads may be formed on a lower section of the container neck, such as in the vicinity of its base, with a section of the neck intervening its lip bead and its threaded section of appreciable axial length and of lesser diameter than the lip bead. Thus, when the internally-threaded bottom annular zone of the cap skirt is telescoped down over the projecting top end of the piston plug and the lip bead the internal skirt bead may be snapped down over the latter to effect the captive mounting without engaging the cap skirt screw threads upon the neck screw threads. When it is then desired to thrust the piston plug forward in the bore of the neck by forward translation of the covering cap on the latter the cap will be pushed down until its internal threads can be engaged with the external neck threads and then rotated to translate the cap axially forward. In this form the engagement of the stop means below the neck shoulder provides captivity of the cap and piston assembly in the outward initial position of the latter, and the screw threaded engagement provides additional captivity in the inward position of the assembly after the thrust thereof.

When the cap skirt is freely slidable down over the neck without rotation for the axial thrust of the piston plug, as is attained in embodiments from which threaded interengagement is omitted, the telescopic skirt of the cap structure may be initially captive in the outward initial position of the piston means by engagement of its internal stop means below the cooperative stop shoulder on the neck. Supplemental captivity may be provided for such telescopic cap structure to be effective after the cap and piston assembly has been thrust inward, and this may be another stop shoulder on the neck, below its first stop shoulder, down over which the stop means in the cap skirt snaps upon the completion of the inward thrust. This is particularly advantageous when the piston means is made separate from the cap structure with the latter telescoped down over the top end or thrust post of the piston means, and with the transverse cap top wall provided with a cannula-receptive hole. If, in such structure, the separate cap should be permitted to slide back to its initial outward

position after forward thrust of the piston's means thereby a recess of large capacity within the cap would be accessible readily through the cannula-receptive hole in the cap top, making possible collection of fouling or contaminating matter within this recess about the top end of the piston post down through which the next syringe needle is to be thrust for the next withdrawal of a medicament load. Captive locking of the cap to its innermost position after inward thrust prevents such fouling.

When the cap and piston plug are captive by such interengaging means, liquid contents of the permanently closed container may be removed through a cannula-receptive hole provided in or a needle-pierceable area of the transverse top wall of the cap, suitably aligned with a needle-pierceable area of the piston plug therebeneath. This permits thrust of a hypoderimc needle therethrough to communicate its bore with the liquid contents.

A further object of the present invention is to provide a form of the device in which the piston plug is captive with respect to the protective cap when they are formed as separate units, the means to attain this end permitting, if desired, relative rotation. As a result, when the protective cap is detached from the container it will pull the piston plug with it, thereby permitting removal of liquid contents by pouring from the mouth of the container. For this purpose, the piston plug may be provided with an annular captive flange which is engaged axially outward over an internal annular shoulder in the skirt of the cap. This shoulder may be defined by an annular groove in the cap skirt adjacent the transverse top wall of the cap with the transverse flange of the piston plug being elastic and snapped thereinto.

A still further object of the present invention is to provide structural embodiments of the device which are readily constructed and permit efficient use and operation for various types of service.

Other objects of the invention will in part be obvious and will in part appear hereinafter.

The invention accordingly comprises the features of construction, combinations of elements, and arrangement of parts, which will be exemplified in the constructions hereinafter set forth, and the scope of the invention will be indicated in the claims.

For a fuller understanding of the nature and objects of the invention reference should be had to the following detailed description taken in connection with the accompanying drawings, in which:

FIG. 1 is an enlarged exploded perspective view of the parts of an embodiment of the admixing storage container of the present invention;

FIG. 2 is a side view of the embodiment shown in FIG. 1, showing the parts in their relative mounted positions and the device loaded for market distribution of the contents, the closure cap and the waist plug being shown in side elevation and the container being shown in axial section;

FIG. 3 is a detailed axial section of the top portion of the device shown in FIG. 2, with parts broken away;

FIG. 4 is a perspective pictorial view illustrating the manipulative "firing" of the device shown in FIG. 2;

FIG. 5 is a perspective view of the inverted FIG. 4 device, illustrating removal of admixed liquid contents;

FIG. 6 is an axial section to enlarged scale of a modified form of the closure means for forms of the container of the present invention;

FIG. 7 is an axial section of the top closure means of another embodiment of the device, with parts broken away, employing the closure means of FIG. 6;

FIG. 8 is an axial section of the top portion of a further modification of the device of the present invention, with parts broken away;

FIG. 9 is a sectional view similar to FIGS. 7 and 8, but with parts in side elevation, of a still further embodiment of the invention;

FIG. 10 is an axial section to enlarged scale of another embodiment of the present invention, showing the separated chambers of the container proper respectively loaded with medicament solids and liquid, and with the closure means located in an initial outward position before "firing" manipulation;

FIG. 11 is an axial sectional view of an axially slidable cap element of the FIG. 10 structure;

FIG. 12 is a sectional view similar to FIG. 10, but with parts broken away, illustrating hydraulic expulsion of the chamber-separating waist plug for communicating the chambers together to allow admixing of their respective contents, this "firing" action being obtained by inward thrust of the cap element of the closure means to move it and the piston plug covered thereby to the illustrated inward positions;

FIG. 13 is an axial section with parts broken away of the top portion of a modified form of the cap illustrated in FIGS. 10 to 12 incl. and the top end of the piston plug which is similar to that shown in FIGS. 10 and 12 except in minor details;

FIG. 14 is an axial section of a modified form of the closure means illustrated in FIGS. 10 and 12, indicating integral connection between the cap skirt and the piston plug, and illustrating a recess closure plug to avoid collecting contaminating matter therewithin while depicting in dotted lines an original position of such closure plug in the molding of this unitary structure;

FIG. 15 is an exploded view of a further modified form of the device of the present invention, showing the cap thereof in axial section and the piston plug and container in side elevation;

FIG. 16 is a side elevational view of the structure shown in FIG. 15, with parts broken away and with the cap shown in axial section, the piston plug and cap being shown in their initial outward positions before "firing" manipulation;

FIG. 17 is a view of the structure of the device of FIGS. 15 and 16, with parts broken away and in axial section, illustrating expulsion of the waist plug for intercommunicating the separated chambers by the inward thrust of the piston plug resulting from the covering cap being telescoped down forcibly on the container neck by screw advance;

FIG. 18 is an axial section of the top portion of the container neck with other parts thereof broken away, the piston plug and a modified form of the thrust cap, illustrating captivity of the latter by a modified form of interengaging structure, and with the cap being of the axially slidable type illustrated in FIGS. 10 to 14 incl.;

FIG. 19 is a bottom end view of the thrust cap of FIG. 18;

FIG. 20 is a view similar to FIG. 18 of a further modified form of the closure, illustrating a variation of the top portion of the container neck and of the covering thrust cap, part of the top end of the neck being shown in side elevation;

FIG. 21 is a view similar to FIG. 18 showing in axial section the thrust cap of FIGS. 10 to 12 incl., a modified form of the piston plug, and illustrating the addition of a second stop shoulder to the container neck to provide supplemental captive means effective after the cap and piston plug have been thrust forward;

FIG. 22 is an axial section similar to FIG. 21, illustrating the relative positions of the parts thereof after the piston plug has been thrust forward in the neck bore by forcible telescope of the cap down about the container neck and showing captivity of the latter by the supplemental captive means;

FIG. 23 is a view similar to FIGS. 18 and 21 showing in axial section a further modified form of the thrust cap of the type illustrated in FIGS. 10 and 21, a further modified form of the piston plug, and illustrating the addition of a second internal captive rib within the cap skirt to provide the supplemental inward captive means which is effective after the cap and piston plug have been thrust

forward, and illustrating an additional internal stop rib within the cap momentarily to resist inward thrust from the initial outward captive position with means assuring rotation of the piston plug by the cap; and

FIG. 24 is an axial section similar to FIG. 23, illustrating the relative positions of the parts thereof after the piston plug has been thrust forward in the neck bore by forcible telescope of the cap down about the container neck and illustrating the captivity of the latter by the supplemental inward captive means.

Referring to the drawings, in which like numerals identify similar parts throughout, it will be seen from FIGS. 1 to 5 incl. that an embodiment of the invention may comprise a container or vial 10 for storage of a liquid ingredient and another ingredient, such as a material miscible therewith, of an ultimate admixture or solution, with these ingredients being segregated in separate chambers 11 and 12 thereof. The container 10 may be in the form of a vial molded from suitable material, such as glass or a plastic non-contaminable of the contents. The top and bottom end sections of the container 10 which respectively form the top and bottom chambers 11 and 12 thereof are separated by an intervening mid-section 13, which may be in the form of a constricted waist to define separating partition means therebetween. The separating partition means or constricted waist 13 has an intercommunicating passage 14 to permit admixture of the liquid 15 in the top chamber with the miscible material or solids 16 in the bottom chamber 12. The intercommunicating passage 14 is of a cross-sectional area appreciably less than that of the adjacent or top portion of the bottom chamber 12 immediately therebelow. The intercommunicating passage 14 preferably is cylindrical and it defines a gate plug seat.

The bottom chamber 12 is closed off on the bottom by an end wall 17 and on the top by an elastic gate plug 18 inserted in the seat 14, between which are confined the mass 16 of miscible material, which may be a suitable solute such as particulate solids soluble in the liquid as the solvent 15, or a liquid miscible with the latter. The gate plug 18 may be in the form of a cylindrical body of elastic rubber-like material having a cross-sectional dimension appreciably less than that of the top adjacent portion of the bottom chamber 12, but greater than that of the passage seat 14. The elastic gate plug 18 is slidably fitted in constricted condition into this cylindrical seat 14 after the solute solids 16 have been loaded into the bottom chamber 12. The constricted elastic gate plug 18 is expellable by pressure out of the seat 14 down into the bottom chamber 12.

The closure means for the container 10 is in a form which includes a tubular loading extension or neck 19, having a cylindrical bore 20 leading to the main portion of the top chamber 11, and it terminates in an annular lip 21 circumscribed about the mouth of the bore. While the tubular loading extension 19 may be of a diameter substantially equal to the diameter of the top chamber 11, for certain service it is preferably constricted to the form of a tubular neck of smaller size. The tubular loading extension or neck 19 is provided externally with a section of screw threads 22 and an annular shoulder 23 therebelow. For this purpose, the top section of the neck 19 may be made thicker so that an annular shoulder 23 is defined as a step between the screw thread-carrying thicker section or annular land and a smaller section 24 therebelow. However, the downwardly facing annular shoulder 23 may, if desired, be provided in the form of the bottom side of an annular bead or rib.

The closure means of the FIGS. 1 to 5 incl. embodiment also includes a piston plug 25 which carries an elastic, elongated, cylindrical piston section 26. For this purpose, the piston plug 25 may be molded as a unitary structure from suitable elastic rubber-like composition, and it may have an integral, enlarged, laterally-extending annular flange 27 at its top end provided with a transverse, flat, top surface 28. The piston plug 25 may have an axial recess 29 extending from its bottom end 30 to the near vicinity of the top end surface, as will be best understood from FIG. 3, so as to define a closing diaphragm 31 medially of its top surface which is readily needle-pierceable. The elastic piston section 26 of the piston plug 25 is a little larger in diameter than the neck bore 20 and it is slidably fitted in constricted condition within the latter in an outward initial poistion, as is illustrated in FIG. 3, with a top portion of the piston plug projecting an appreciable distance beyond the neck lip 21. Thus the quantity of liquid 15 is confined or stored in the top chamber 11 between the gate plug 18 and the piston plug 25.

The closure means of the embodiment of FIGS. 1 to 5 incl. is completed by a cap 32 which protectively covers the projecting top portion of the piston plug with the cap located in an outward mounted position, as will be seen from FIG. 3. The covering cap 32 has a transverse top wall 33 and an internally-threaded cylindrical skirt 34 depending therefrom. The internally-threaded cylindrical skirt 34 is threadably engaged with the screw threads of the threaded neck section 22, leaving exposed an appreciable length of the lower neck section 24 of reduced diameter below bottom edge 35 of the cap skirt. When the cap 32 is made of malleable metallic material, such as by being drawn from aluminum, the bottom edge 35 of its skirt 34 may be constricted by spinning it inward beneath the annular neck shoulder 23, so as to limit outward movement of the cap and provide for substantially permanent mount thereof to the container while allowing limited inward travel along the reduced neck section 24. The transverse top wall 33 of the protective cap 32 is provided with a central hole 36 which is aligned with or overlies the pierceable diaphragm 31 of the piston plug 25.

The embodiment of the device illustrated in FIGS. 1 to 5 inclusive may be loaded in the following manner. A quantity of the miscible material or solids 16 will be loaded successively down through the neck bore 20 and the constricted intercommunicating passage 14 into the bottom chamber 12. The gate plug 18 will then be inserted down through the neck bore 20 and forced into the passage or seat 14 to close off the top end of the bottom chamber 12. The top chamber 11 will then be loaded with a quantity of liquid 15 through the neck bore 20, the quantity being such as to assure that with inward thrust of the piston plug 25 in the neck bore 20, sufficient hydraulic pressure will be created in the top liquid housing chamber 11 to expel the gate plug 18 out of its seat 14 into the bottom chamber 12. This may be assured by introducing a quantity of the liquid 15 which is greater than a predetermined cubic capacity of the liquid housing chamber 12 (with the latter including the bottom portion of the neck bore 20) to which it may be reduced by full inward thrust of the piston section 26 down into the bore. The loader should avoid trapping of an undue quantity of air in a head space above the body of liquid 15 at the time the elastic piston section 26 of the piston plug 25 is forcibly inserted into the neck bore 20. Due to the compressibility of gases, such as air, if an excessively large amount thereof is trapped in the top liquid chamber it may appreciably reduce the effective expelling pressure applied to the gate plug 18. To avoid this possibility the loader may insert within the neck bore 20 along the side of the piston section 26, as it is being inserted, a suitable bleed tube which may then be withdrawn. As a result, the finished package of FIG. 2 is produced for market distribution.

It will thus be seen that in the FIGS. 1 to 5 embodiment, and particularly by reference to FIG. 3, means is provided on the tubular loading extension or neck 19 below its lip 21 which defines a downwardly facing first stop shoulder 23. The tubular depending skirt 34 of the cap 32 coaxially surrounds the piston plug means 25 and constitutes therewith a piston closure assembly in the form

of piston means covered by cap structure 32. The cap skirt 34 and the piston plug 25 define therebetween an elongated annular space in which the lipped top portion of the tubular loading extension or neck 19 is located in a forward initial position where it is telescopically lapped by a lower portion of the cap skirt 34. The unoccupied portion of this space outward or above the lipped top portion of the neck 19 is of a longtudinal depth at least equal to the predetermined thrust distance through which the piston section 26 is to travel in the neck bore 20. The top end of the cap skirt 34 is associated with the top portion or annular flange 27 of the piston plug 25 in a manner closing off the outer or top end of the annular intervening space, this being attained by the seating of the transverse top wall 33 of the cap against or down upon the top end surface 28 of the piston plug. This same association will cause the piston section 26 to be thrust inwardly or downwardly in the neck bore 20 by the telescopic advance or lowering of the cap skirt down about the neck 19 attained by screw threading rotation of the cap 32 in an advancing direction. Additional means are carried by this piston closure assembly which defines a cooperative upwardly-facing second stop shoulder, this being in the form of the top surface of the inner lateral flange formed by inwardly spinning the bottom edge 35 of the cap skirt 34. The resulting pair of stop shoulders 23 and 35 are longitudinally aligned in opposed relation for substantial abutment in the outward initial position of the piston closure assembly, as is shown in FIG. 3, to constitute an outward closure captive means. At least one of these stop shoulders, 23 or 35, extends entirely circumferentially about the neck bore 20, and it will be seen that thus this closure captive means effectively resists non-rotary pull removal of the piston closure assembly in all angular positions thereof, while also resisting unscrewing removal. Incidentally, the engagement of the neck thread 22 with the internal threads of the cap skirt 34 also effectively resists non-rotary pull removal and retraction of the piston closure assembly in all of its angular positions, while serving an additional useful purpose explained hereinafter.

In operation of the embodiment of FIGS. 2 and 3 when in its initial loaded and ready condition, there illustrated, one may "fire" the device or intercommunicate its top liquid housing chamber 11 with its bottom solids-containing chamber 12 by grasping the container 10 with one hand and the cover cap 32 with the other, such as in the manner illustrated in FIG. 4, and rotating the cap forward for inward screw advance by threading its skirt 34 down over the threaded section 22 of the container neck 19, such as to the dotted line position 320. As a result, the cap 32 applies thrust to the top end 28 of the piston plug 25 to slide its piston section 26 down in the neck bore 20, thereby suitably reducing the cubic capacity of the liquid housing chamber. The hydraulic pressure developed thereby quickly expels the gate plug 18 into the bottom chamber 12 from out of its intercommunicating passage seat 14, such as is indicated in dotted lines at 118 in FIG. 4. Consequently, the body of liquid 15 will spill down into the bottom chamber 12 for admixture with the miscible material 16 in the latter. Thorough admixture of the ingredients, such as dissolving the solids 16 into the liquid 15, may then be attained by shaking the "fired" device to produce the ultimate liquid solution.

When the device of FIGS. 2 and 3 has been fired in the described manner with inward screwing of the cap 32 on the neck 19 to the extent possible the lateral, elastic top flange 27 of piston plug 25 will be clamped between the inner face of the cap transverse top wall 33 and the container lip 21 to gasket the container mouth securely closed. Even though ingredients are such as to develop an elevated pressure within the closed container, or gaseous medium be injected, this closure will be maintained leak-proof by this gasketing.

The embodiment of FIGS. 1 to 5 incl. also provides between the tubular loading extension or neck 19 and the piston closure assembly (consisting of piston 19 and cap 32) a supplemental interengaging stop means which is effective in the inward "fired" position closure assembly at the advance end of the forward thrust of the piston section 26 down into the neck bore 20, so as to constitute an inward closure captive means. This consists of the interengagement of the external neck male thread 22 with the internal female thread within the cap skirt 34. At least one of these supplemental stop shoulders extends entirely circumferentially about the neck bore 20, which is satisfied by the fact that either the external thread 22 or the internal thread in the cap skirt 34 extends more than 360° about the neck axis, and thus non-rotary pull retraction of the pistion closure assembly from its inward "fired" position is effectively resisted in all angular positions of this assembly. Thus, the opposed cooperative stop annular shoulders 23 and 35 provide a first closure captive means in the outward initial position of the piston closure assembly and the threaded engagement provides a second closure captive means in the inward "fired" position of the piston closure assembly, which are effective to resist non-rotary pull removal and retraction of this assembly with respect to the container neck.

In the event that the liquid vehicle 15 and the miscible material 16, such as medicinal solids soluble in the liquid vehicle, are intended to be admixed for the preparation of an ultimate parenteral liquid composition or solution, hypodermic doses may be removed successively therefrom with a hypodermic syringe which is to be used in the injections. Such a hypodermic syringe is partially indicated at 37, and includes a piston-equipped barrel 38 carrying a conventional hollow hypodermic needle or cannual 39. The operator thrusts the needle 39 through the central hole 36 in the top transverse wall 33 of the cap 32 to pierce through the diaphragm 31 and communicate the needle bore with the interior of the container 10, such as by way of the recess 29. Thus, with the fired device inverted, such as to the position depicted in FIG. 5, a load or dosage of the parenteral composition 15–16 may be withdrawn into the chamber of the syringe barrel 38 for injection after the needle has been withdrawn. Upon withdrawal of the needle 39 from the slit cut through the diaphragm 31, the slit closes for protection of the remaining contents of the container 10 for subsequent use or repeated withdrawal in like manner of successive dosages.

It will be seen that, since the inside face of the cap top wall 33 is kept abutted against the flat top end 28 of the piston plug 25 in the outward initial position illustrated in FIG. 3 by virtue of the interengagement of the captive shoulder 23 by the captive inspun flange 35 and also by the supplemental captive means provided by the threaded engagement of the internally threaded cap skirt 34 with the external neck thread 22 in the inward "fired" position of the piston closure assembly, the interior of the cap and external surfaces of the piston plug exposed therein will be kept free from contaminating matter. Thus, the only possible place for collection of such contaminating matter is the small shallow recess defined by the central hole 36 in the cap top wall and the small area at 31 of the plug top surface 28 which bottoms this hole. Accordingly, contamination of a hypodermic needle which is thrust through to communication of its bore with the interior of the container for withdrawal of a successive dosage can be easily avoided by swabbing this small shallow recess with a suitable germicide, such as alcohol saturating a wad of cotton, prior to the subsequent thrust of the needle down through this recess.

FIGS. 6 and 7 illustrate a modified form of the closure means for such a dual-chamber admixing storage container. As in therein illustrated at 125, the piston plug may be in the form of a hollow bulb of elastic, needle-pierceable material, such as a suitable rubber-like com-

position. This bulbous piston plug 125 has an enlarged hollow section 126 suitably connected to a lateral top flange 127 by a relatively stiff, intervening hollow neck 40. The bottom end of 41 of the bulbous piston section 126 is needle-pierceable. The cover cap 132 is somewhat similar in construction to that at 32 in the FIGS. 1 to 5 incl. embodiment, having a transverse top wall 133 provided with a central hole 36 and a depending cylindrical, internally-threaded skirt 134. In the loading of a container of a type similar to that illustrated in FIGS. 1 to 5 incl., the bulbous piston section 126 will be inserted in the bore 20 of the tubular loading extensions 119, after the top chamber of the container has been loaded with the body of liquid 15. This action reshape the bulbous piston section 126 substantially to the shape indicated in FIG. 7, due to internal container pressure, so that there is a zone of contact 42 of appreciable width with the wall of the bore 20.

The firing action of such a device embodying the closure means of FIGS. 6 and 7, is similar to that described above and involves the screwing of the cap 132 down about the tubular loading extension 119 for forward thrust of the piston section 126 in the tubular extension bore 20. In all positions of the cap 132 effective piston closure captive means is provided by the screw-threaded engagement to prevent non-rotary pull retraction or removal thereof.

In order to avoid undue collection of dust within the hollow chamber of the bulbous piston plug 125 through the cap axial hole 36 during storage, the latter may be closed off by a diaphragm provided by a thin needle-pierceable disc 43 interposed between the piston plug top flange 127 and the transverse end wall 133 of the cap. Such a diaphragm disc may be cemented to the bulb flange 127, or held in position between these elements by suitably anchoring the piston plug 125 to the cap, which may be by way of captive interfitting means illustrated in FIG. 8 and described hereinafter. It should be apparent from FIG. 7 that the externally-threaded tubular loading extension 119 may be a top portion of the liquid chamber and thus of substantially equal diameter. The lateral top flange 127 of the piston plug means 125 serves as the gasket between the cap top wall 133 and the container lip 121.

As is illustrated in FIG. 8, a modified form of the device may include a piston plug 225 which has a solid piston section 226 inserted for snug sliding action in the bore 20 of the tubular loading extension or neck 219. In this form, after the device has been fired by forward thrust of the piston section 226 down in the neck bore 20 with threaded forward rotation of the cover cap 232, to screw its internally-threaded skirt 234 down upon the externally-threaded section 222, the admixture contents of the container may be removed by pouring it out of the mouth of the neck bore 20. When the piston plug 225 is molded from elastic material, such as a suitable plastic or rubber compound, the lateral top flange 227 thereof may be clamped as a gasket between the cap top wall 233 and the container lip 221 as the firing action is completed. The pouring removal procedure requires withdrawal of the piston plug 225 from the neck bore 20. For this purpose, the piston plug 225 may be captively mounted within the cover cap 232, such as by snapping its flexible, elastic, lateral head flange 227 into an internal annular groove 44 in the cap adjacent the inside face 45 of the top transverse wall 233 thereof. The internal annular groove 44 in the cap skirt 234 provides an internal annular plug-captive shoulder 46, which is located axially inward of the inner face 45, outwardly beyond which the annular captive flange 227 of the piston plug is engaged. Thus, when the cap 232 is threadably disengaged or unscrewed from off of the neck 219 the piston plug 225 is pulled therewith by its captive flange 227 to open up the neck bore 20 for spilling of the container contents therethrough.

It is to be understood that, if desired, the liquid contents or ultimate solution of the embodiment of FIGS. 1 to 5 incl. may be removed from the container 10 by spilling through the neck bore 20 if the piston plug 25 is removed with complete forced detachment of the cap 32 from the neck 19. For this purpose, the head flange 27 of the piston plug 25 may be interfitted in an annular groove in the cap skirt 34 in a manner such as that proposed in FIG. 8. The engagement between the withdrawal-limiting shoulder 23 and the constricted bottom edge 35 of the cap skirt 34 do not prevent this operation since, if the cap 32 be retracted further by continued unscrewing thereof, the constricted bottom edge may be forced up with expansion over this shoulder and the screw threads 22. If the cap is drawn from relatively highly malleable metallic material, such as aluminum, the constricted bottom edge 35 can be distorted and swelled out to pass up over these obstructions with continued retraction of the cap, and if such a cap be molded from plastic material having some elasticity the constricted bottom edge flange may be elastically swelled by such forcing action to permit the cap skirt to be freed from the container neck. The captive piston plug will be detached with the cap.

It is proposed in FIG. 9 to embody the present invention in a device featuring a reversal of parts. In this embodiment the screw threads are provided at 322 internally of the bore of the tubular extension 319. Preferably, the internally-threaded section 322 is located adjacent the lip 321 and is of an internal diameter appreciably less than the unthreaded section 320 therebelow. The unthreaded section 320 of the tubular extension bore is substantially cylindrical. The piston plug and cap assembly of the FIG. 9 structure includes a piston plug 325 and a protective covering cap 332, which may be integral with each other as a result of molding this assembly as a unit from suitable material, such as a plastic or rubber compound which may have a degree of elasticity. The depending portion 326 of the piston plug 325 which is engaged in the threaded section 322 of the tubular extension bore is provided with male threads mating with the female threads in the latter.

If the tubular extension 319 of the container of the FIG. 9 embodiment is of relatively rigid material, such as glass or a suitable plastic having an appreciable degree of rigidity, a fluid-tight fit between the externally-threaded piston section 326 and the internally-threaded section 322 of the tubular extension bore may be assured by making the threaded piston section slightly oversize. Thus, as the cap 332 is rotated forward to screw the threaded piston section 326 down into the threaded bore section 322, the piston section will be rotated therewith and translated axially inward with maintenance of the fluid-tight fit between the mating threads.

If it is desired to have a loose fit between the mating threads of the piston section 326 and the internally-threaded bore section 322 of the FIG. 9 embodiment, provision may be made for suitably gasketing the piston section to the bore wall by other means. For example and as is illustrated in FIG. 9, the unthreaded section 320 of the bore may be enlarged below the internally-threaded section 322 and an extension 50 on the bottom end of the threaded piston section 326 may be provided with an annular groove 51 in which is seated a suitable gasketing ring 52, such as an O-ring, to be wiped along the bore cylindrical section 320 as the piston section is threaded inwardly. The O-ring 52 will thus maintain a fluid-tight engagement with the bore wall, and it constitutes an elastic annular zone of the piston section 326 having a greater diameter when free than does the transverse cylindrical section 320 of the tubular extension bore, so that it has a slidable fit in constricted condition therewithin between the outward initial position of the piston plug and cap assembly illustrated in FIG. 9 and the inward fired position of this assembly, i.e., throughout

the intermediate axial translation thereof. The resulting piston action will create the required hydraulic pressure to cause the gate plug, such as that illustrated at 18 in other figures, to be expelled from its seat 14 down into the bottom chamber.

When the piston plug and cap assembly of the FIG. 9 embodiment is molded as a unit from elastic material, ultimate engagement of the annular inner face 53 with the lip 321 will gasket the closure of the mouth of the tubular extension 319 in a fluid-tight manner when the piston plug and cap assembly are screwed inwardly as far as is possible. This gasketing may be attained even though the piston plug and cap assembly be molded from relatively rigid material by inserting against the annular face 53 a suitable gasketing washer. The cap 332 may be protectively sealed to the tubular extension 319 in any suitable manner, such as by a shrinkable cellulose band 54. Such a sealing band 54 may be removed in the usual manner by tearing it away, to permit the firing manipulation of the piston plug and cap assembly.

It will be understood from FIG. 9 that since the diameter of the top section of the bore 320 which carries the internal threads 322 is at all points appreciably less than the diameter of the lower bore section 320, an intervening downwardly-facing annular shoulder is provided thereby. This annular shoulder is located in opposed relation to the top side of the O-ring gasket 52. Thus these opposed annular shoulders provide aligned cooperative stop means which effectively provides captivity of the piston plug and cap assembly in the outward initial position of the latter. When the cap skirt 334 is rotated forward in an advancing position to "fire" the device, the threaded engagement between the externally threaded plug 326 and the internal neck thread 322 provides the desired captivity of the piston plug and cap assembly in the inward "fired" position. These closure captive means effectively resist non-rotary pull removal of the piston closure assembly in all annular positions thereof, both in the outward initial position and in the inward "fired" position.

It is to be understood that if it is desired to withdraw a dosage of liquid contents from an embodiment of the device as is illustrated in FIG. 9 one may provide the piston screw plug 326 with a suitable axial withdrawal recess similar to that illustrated at 29 in FIG. 3, the top end of such recess terminating short of thee top surface 333 of the cap 332 there to provide a thin section which may serve as a needle-pierceable diaphragm.

The gasketing feature, and others, of FIG. 9 may be embodied in a closure of the general type illustrated in FIG 8. For example, if the cap 232 and piston plug 225 of the FIG. 8 structure be integrally molded from plastic or a rubber compound having an appreciable degree of rigidity (the integral formation being the equivalent of the captive anchorage of this piston plug to the cap), the fluid-tight fit of the piston plug to the wall of bore 20 may be attained by an interposed gasket, such as of the type illustrated at 51 and 52 in FIG. 9. In other words, since the piston section 226 of such a substantially rigid piston plug 225 desirably may have an O.D. less than the I.D. of the bore 20 for ready insertion, the lower end of this piston section may be provided with an annular groove in which, is seated a gasket ring having a sliding fit with the bore wall. If it is desired to provide such a piston plug and cap assembly with an axial passage for withdrawal of contents by a cannula, sucs passage may be an axial hole molded therethrough and closed off by a pierceable diaphragm. This diaphragm may be in the form of a thin disc of elastic material having its marginal edge extending around the marginal zone of the bottom end 230 of the piston section and up to the gasket ring for anchorage thereto. This closing pierceable diaphragm disc may be stretched across the inward end of this axial hole or it may have a central cup-shaped area which extends up into the hole to the top end of the central hole.

In the embodiment of FIGS. 10 to 12 incl. the container 10 is similar to that shown in FIGS. 1 to 5 incl., except for the tubular loading extension or neck 419 thereof. The neck 419 is provided with axial bore 20 communicating to the top chamber 11 and terminating at neck lip 421 where it is circumscribed by an annular rib or bead 60 which provides a downwardly-facing annular stop shoulder 423. Piston plug 425 is generally similar to that shown at 25 in FIGS. 1 and 3, being provided with a piston section 426 and the axial recess 29. The flat top end 28 of the piston plug 425 is provided with a shallow target dimple 61, between which and the top end of the recess 29 is defined a needle-pierceable diaphragm 431.

In the embodiment of FIGS. 10 to 12 incl. the piston closure assembly includes the piston plug 425 and a separate cap structure 432 which houses and covers the piston plug. The cap 432 preferably is molded from elastic plastic material, such as polyethylene, if the container 10 be made of or molded from rigid material, such as bottle glass. Cap 432 has a tranverse top wall 433, the underface 453 of which preferably is flat and abutted against the flap top end 28 of the piston plug 425. The cap top end wall 433 may be provided with a central hole 36, aligned with the target dimple 61 and recess 29, down through which a withdrawal cannula or hypodermic syringe needle may be thrust to remove a charge of liquid parenteral mixture.

Cap 432 is provided with a cylindrical sidewall or depending skirt 434 molded at its top end integral with the transverse top wall 433. The internal diameter of the depending skirt 434 preferably is at least as great as the outer diameter of the lip bead 60 or slightly larger, so as to permit free telescope of the cap down about the container neck 419. The bottom edge of the cylindrical or tubular cap skirt 434 is provided with an internal annular rib or constriction 435 of an internal diameter less than the outer diameter of the lip bead 60 for alignment with the latter to serve therewith as a pair of opposed captive stop shoulders. The skirt bottom edge 62 preferably is frusto-conical in shape so as readily to be seated concentrically over the lip bead 60 of the container neck 419. Due to the elasticity of the cap skirt 434 the internal annular rib 435 may be stretched or snapped down over the container lip bead 60 with application of downward axial force applied to the cap top wall 433.

The loaded condition of the FIGS. 10 to 12 incl. embodiment is illustrated in FIG. 10, in which the solvent liquid 15 substantially fills the top chamber 11 and the medicinal solid solute 16 is located in the lower chamber 12, with segregation thereof by the waist plug 18 confined in constricted seat 14. The piston plug 425 is shown located in its outward initial position with its piston section 426 effectively plugging the outer portion of the neck bore 20. The parts are held in these relative positions by virtue of the engagement of the internal annular cap rib 435 beneath the annular shoulder 423 of the neck bead 60, these opposed and abutted stop shoulders together constituting an outward closure captive means.

Not only does the cap 432 serve to keep the piston plug 425 captive and in its initial outward position, but also protectively covers it. While any small amount of contaminating matter that may collect in the target dimple 61 and hole 36 may be cleaned out readily, additional precaution may be simply taken to avoid such collection by substituting for the needle access hole 36 in the cap top end wall a target dimple 161, similar to 61 of FIG. 10, as is proposed in FIG. 13. As a result, a relatively thin needle-pierceable section 63 of the cap top end wall 533 remains intact above the top end 28 of the piston plug 525. Such protective cover and thrust cap 532 is thus imperforate at all points, so as to assure that no contaminating matter will collect on any exposed portions of the piston plug 525 within the cap skirt 534. It is to be understood that the cap 532 of FIG. 13 is to be provided with captive means, such as that illustrated in FIGS. 10 and 12 incl. Exclusion of foreign matter with-

in the cap skirt may be assured by a relatively close frictional fit of minor degree between the lip bead 60 and the internal annular rib or constriction 435 within the cap skirt 434. It will be noted in FIGS. 10 and 12 that line contact is substantially maintained between the inner wall of the cap skirt 434 and the radially outer edge of the container lip bead 60.

In operation of the embodiment illustrated in FIG. 10, or as modified if desired by the proposal of FIG. 13, one applies pressure to the broad top end of the piston closure cap 432 to advance the cap skirt 434 down about container neck 419 and to thrust the piston plug 425 forward or down in the neck bore 20, to create sufficient hydraulic pressure in the top chamber 11 as to expel the waist plug 18 into the bottom chamber 12. This resulting intercommunication of the top and bottom chambers 11 and 12 is illustrated in FIG. 12, with the piston plug there shown in its inward "fired" position.

As will be seen from FIG. 14, and as was previously proposed in FIG. 9, the piston plug may be made integral with the cap structure, such as by molding them together from suitable rubber-like material or elastic plastic, e.g., polyethylene. It will be seen from FIG. 14 that the tubular cap skirt 634 may be provided with a captive bottom edge constriction 635 to be engaged below stop shoulder means on the container neck, such as the annular downwardly-facing shoulder 423 of the lip bead 60, shown in FIGS. 10 and 12. The container lip 421 and its annular external bead 60 are slidably received in the annular space 64 which is of a depth at least equal to the predetermined thrust distance or intended stroke of the piston plug in the neck bore, as is the case in the FIGS. 10 to 12 incl. embodiment.

In the FIG. 14 cap and piston assembly it is proposed that the needle-pierceable diaphragm 631 be provided at the lower end of the piston section 626 by forming the recess 129 from the top end 633 downward. In order to avoid collection of fouling matter within the resulting socket it is proposed that the mouth of the latter be enlarged and undercut, such as is proposed by way of illustration at 64, so as to receive and temporarily hold therein a snap button 65. The snap button 65 may be made of the same elastic plastic material as is the cap and piston assembly 632 and may be molded integral therewith, such as in the position 165 indicated in dotted lines and connected to the cap top 633 by an integral web 66 indicated in its initial position in dotted lines at 166. The closing button 65 may also be provided with an integral lift tab 67 to facilitate removal from the shaped socket 64 as a preparatory operation preceding the insertion of a syringe needle into the socket 129 and down through the diaphragm 631 for withdrawing a dosage from the container.

The embodiment of FIGS. 1 to 5 incl. illustrates as first captive means to hold the piston closure assembly in its initial outward position, opposed and abutted annular shoulders 23 and 35, and supplemental captive means to hold this assembly in its inward "fired" position in the form of the screw-threaded engagement of the threaded cap skirt 34 with the thread 22 on the container neck 19, with this supplemental inward captive means being located axially outward of the first captive means. However, the locations of these paired and separate outward and inward captive means may be reversed. Such a reversal of these structures is shown in FIGS. 15 to 17 incl.

In the FIGS. 15 to 17 incl. embodiment the tubular loading extension or neck 719 of the chambered container 210 is provided at its lip 721 with an annular external bead 160 having a predetermined outer diameter. The lower neck portion 724 is provided with an annular land 70, which may have an outer diameter about equal to or slightly greater than that of the lip bead 160, and it carries a male screw thread 722, which extends more than 360° thereabout.

The piston plug 25 of the FIGS. 15 to 17 incl. embodiment may be similar to that shown in FIG. 1, having a lower piston section 26 which is to be plugged into the neck bore 20 with the bottom end 30 thereof located at an outward initial position, such as that indicated in dot-dash lines at 72 in FIG. 15, as is illustrated in FIG. 16. As in the embodiment of FIGS. 1 to 5 incl. the medicament solids 16 are loaded in the lower chamber 12 which is segregated from the upper chamber 11 by gate plug 18 confined in the constricted seat 14. The liquid vehicle of the ultimate parenteral fluid mixture, such as that indicated at 15 in FIG. 17, may be stored in the upper chamber 11, such as to the point 72.

The piston closure assembly of the FIGS. 15 to 17 incl. embodiment includes the piston plug 25 and a separate cap structure 732. The cap 732 has a transversely-extending top end wall 733 provided with a central hole 36 and a depending tubular or cylindrical skirt 734 preferably integral therewith, as may be attained by molding the cap as a unitary structure from suitable material. If the container 210 is molded from bottle glass the cap 732 will be molded from suitable elastic material, e.g., elastic plastic, such as polyethylene. The ower portion or terminal zone 73 of the cap skirt 734 is provided with internal screw threads 340 to mate with the external screw threads 722 on the neck zone or land 70, and this internally-threaded cap skirt zone is of a minimum internal diameter at all point at least equal to the external diameter of this neck land for free engagement down thereover upon threaded rotational advance. The minimum internal diameter of the internally-threaded cap skirt zone 73 at all points may also be at least equal to or slightly larger than the external diameter of the rim bead 160 so as to be freely telescoped down thereover. Between the transverse top end wall 733 and the internally-threaded zone 73, the cap skirt 734 is provided with an internal constriction or annular rib 735 which is of an internal diameter appreciably less than the external diameter of the rim bead 160, so as to require stretching to be snapped down thereover.

With the chambers 11 and 12 of the container 210 of the FIGS. 15 to 17 incl. embodiment suitably loaded and segregated the top chamber carrying the liquid vehicle 15 may be closed by inserting the piston section 26 of the piston plug 25 into the mouth of the neck bore 20, as is illustrated in FIG. 16. In such initial position of the piston plug 25 its top portion extends an appreciable distance above the beaded lip 721 of the neck 719, as shown in FIG. 16, the length of the exposed portion between the top flange 27 thereof and the neck lip 721 being the thrust distance. The internally-threaded lower zone 73 of the cap skirt 734 is then telescoped down over the lip bead 160 until the internal rib 735 rests upon the latter. With momentary application of thrust to the top end 733 of the cap its internal rib 735 may be snapped down over the rim bead 160 to engage up against the bottom annular shoulder 723 of the latter, thereby serving together as outward captive means to hold the piston plug 25 in its initial outward position while protectively covering it. The axial hole 36 in the cap top end wall 733 is effectively closed by abutment of the bottom face 753 of the latter to the top surface 28 of the piston plug 25.

In operation of the completed package illustrated in FIG. 16, the operator will apply additional slight thrust to the cap top end wall 733 and rotate it in an advancing direction, such as that illustrated by the arrows 74 in FIG. 16, until the male thread 722 is interengaged with the female thread 340. Continued advancing rotation of the cap 732 will cause it threadably to be telescoped further down over the container neck 719, so as to advance the piston section 26 of plug 25 in the neck bore 20, thereby creating hydraulic pressure in the top chamber 11 to expel the segregating waist plug 18 into the lower chamber 12, as is illustrated in FIG. 17. This advance of

the protective cap 732 is ultimately stopped by jamming the transverse annular flange 27 of the piston plug 25 down against the neck lip 721, as is shown in FIG. 17. In this inward "fired" position of the closure piston assembly the threaded engagement between the neck male thread 722 and the cap skirt female thread 340 provides the second or supplemental inward captive means.

It will thus be seen that in the FIGS. 15 to 17 incl. embodiment, the outward captive means is provided by the internal cap rib 735 and the external lip bead 160 with abutment of the former up against the annular shoulder 723 of the latter. These opposed and aligned stop shoulders both extend entirely circumferentially about the neck bore 20 and effectively resist non-rotary pull removal of the piston closure assembly or its cover cap 732 in all angular positions of the latter. The supplemental stop shoulders provided by the external neck thread 722 and the internal cap skirt thread 340 provide in the inward position of the piston closure assembly ininterengaged captive means which also extend entirely circumferentially about the neck bore 20 and effectively resist non-rotary pull retraction of the piston closure assembly in all angular positions thereof.

It is to be understood that so long as one of the stop shoulders of either the outward captive means or the inward captive means extends entirely circumferentially about the neck bore the other cooperative stop shoulder which is abutted thereagainst need not do so in order to provide this effective captive function. For example, as is illustrated in FIGS. 18 and 19 the stop shoulder means on the container neck 419 may be in the form of the annular lip bead 60 while the cooperative stop shoulder means of the protective cover cap 832 may be in the form of a plurality of localized projections or nibs 835 distributed about the interior surface of the tubular cap skirt 534. As is illustrated in FIG. 19, three such nibs 835, located about 120° apart, will effectively serve this function. Conversely the cap may carry its stop shoulder means in the form of an internal rib or constriction 935, as is illustrated in FIG. 20, and a plurality of localized projections or nibs 260 may be provided on the external surface of the container neck 919 in the vicinity of its lip 921, in substitution for the lip bead 60. Three such nibs 260 may be provided for this purpose when located about 120° apart. In the FIGS. 18 and 19 embodiment the lip bead 60 of the outward captive means extends at least entirely circumferentially about the neck bore, while in the FIG. 20 embodiment the internal constriction or cap skirt rib 935 satisfies this requirement.

The embodiments illustrated in FIGS. 1 to 5 incl., FIG. 9, and FIGS. 15 to 17 incl., all provide both outward captive means and inward captive means which respectively anchor the cap in the initial outward position and alternatively in the inward "fired" position. Such pair of alternately effective captive means may be embodied in a structure of the type illustrated in the FIGS. 10 to 12 incl. embodiment, such as in the manner proposed in FIGS. 21 and 22. For this purpose the container neck 1019 is provided with another external bead 1060 axially spaced below the lip bead 60. Thus, as is illustrated in FIG. 21, in the outward initial position of the piston closure assembly, consisting of the piston plug 625 and the protective cover cap 432, the internal elastic constriction or annular rib 435 of the cap is located beneath and abutted up against stop shoulder 423 provided by the lip bead 60, to serve as the outward captive means. When the piston section 626 of the piston plug 625 is thrust forward or down into the neck bore 20 to the inward "fired" position illustrated in FIG. 22, by application of thrust upon the top end wall 433 of the cap 432 the elastic internal constriction or annular rib 435 is stretched and snapped down over the lower annular neck bead 1060 to engage beneath the annular stop shoulder 1023 provided by the latter to serve as the inward captive means.

If it is desired to minimize tendency of localized fouling when an access hole 36 is provided in the top end wall of an embodiment of the protective cap of the present invention, this may be accomplished either in the manner proposed in FIGS. 13, 18 and 20, by substituting a target dimple 161 for such hole, or by other means proposed in FIGS. 21 and 22. The piston plug 625 may have its top end superposed by a coaxial post 75 which snugly fits within the cap axial hole 36. The elasticity of the plastic cap 432 and of the rubber-like material from which the piston plug 625 is molded serve to assure such snug fit and closure of the access hole. The piston plug post 75 may have its top end provided with the target dimple 61 to guide piercing of a hyprodermic syringe needle down through the piston plug to communicate with the recess 29 for withdrawal of a parenteral dosage.

FIGS. 23 and 24 illustrate that provision for the outward initial captive means and the inward supplemental captive means may be provided within the elastic plastic cap skirt, and designed alternatively to cooperate with the annular lip bead of the container neck. Thus, the structure illustrated in FIGS. 23 and 24 is in large measure a reversal of parts of the captive means illustrated in FIGS. 21 and 22, supplemented by other features here described.

In the FIGS. 23 and 24 embodiment the inverted cover cap 1032 is provided with a transverse top end wall 1033 having an underface 1053 and a central access hole 36. A cylindrical cap skirt 1034 is molded integral with and depends from the annular edge of the top end wall 1033, and this skirt terminates in the frusto-conical bottom edge 62 so shaped as to define the internal annular bead 435 having an internal diameter (X) appreciably less than lip bead 60 of the container neck 419. The interior zone of the depending skirt 1034 immediately below the underface 1053 of the transverse top end wall 1033 preferably is shaped to be other than circular, such as polygonal, to provide a polygonal socket 76. At a point relatively a short axial distance below the shaped socket 76 the depending cap skirt 1034 is provided with an internal annular rib 77 to serve as captive shoulder structure of initial position outward captive means, and the internal diameter (X) of this rib may be substantially equal to the internal diameter of the captive terminal rib 435, although it may be slightly larger or slightly smaller. Intermediate the internal annular ribs 77 and 435 the depending cap skirt 1034 preferably is provided with a third internal annular rib 78 to serve as stop means, hereinafter described, and preferably it is of slightly greater internal diameter (Y).

The piston plug 725 is similar to that illustrated at 25 in FIG. 3, preferably being molded of elastic rubber-like material, having an access recess 29 and a needle-pierceable diaphragm 731 intervening the top end surface 728 and this recess. The top end of piston plug 725 is provided with an annular flange 727 which is shaped complementary to the shaped internal cap socket 76, so as readily to seat therein and permit plug rotation by rotation of the protective cover cap 1032.

Let it be assumed that the container 110 is preloaded in a manner previously described, with the top chamber 11 substantially filled with liquid vehicle. The neck bore 20 is effectively plugged by the piston section 726 of the piston plug 725, and may be located therein in the initial position illustrated in FIG. 23, with an appreciable top portion or section of the piston plug extending above the neck lip 721. The projecting portion of the piston plug 725 is protectively covered by the inverted cover cap 1032, with the plug top end surface 728 abutted snugly against the undersurface 1053 of the cap top end wall 1033, thereby effectively closing the access hole 36, and with the shaped plug top flange 727 snugly seated in the comple-

mentary shaped cap skirt 76. In these relative positions of the parts, the upwardly-facing shoulder defined by the bottom internal captive rib 435 engages the downwardly-facing shoulder 423 defined by the undersurface of the lip bead 60, thereby providing the outward initial position captive means. Simultaneously, the relative shallow internal stop bead 78 engages a stop shoulder defined by the upper surface 79 of the lip bead 60. The function of this stop means is for the purpose of giving some resistance to downward thrust of the cover cap 1032 about the container neck 419 which would cause inward thrust of the piston plug 725 forward in the neck bore 20. This stop means thus prevents accidental "firing" of the device prior to the time intended for effecting admixture of the contents of the two chambers of the container, while giving only minor resistance to the required "firing" thrust when desired.

When thrust is manually applied to the cap top end wall 1033 it first causes the elastic internal stop rib 78 to be compressed for slipping down and snapping below the container neck lip bead 60. Thereafter the internal captive rib 435 and this stop rib 78 will be freely slidable for telescopic advance down about the container neck 419 until the supplemental internal captive rib 77 is brought down to engagement with the lip bead 60. Continued thrust compresses the internal rib 77 so that it is snapped down to below the lip head 60 to constitute therewith the inward supplemental captive means, thereby holding the piston plug and cap parts relative to the container neck in the "fired" positions illustrated in FIG. 24. As previously explained, such action creates hydraulic pressure in the top chamber 11 to expel the waist plug into the bottom chamber, thereby permitting the liquid vehicle in the former to spill into the latter for admixing with solids housed in the lower chamber. As a result, the underface of the top end flange 727 of the piston plug is lowered to snug engagement of the neck lip 721 and the internal captive rib 77 is snapped down to beneath the lip bead 60 to provide the supplemental inward captive means for resisting retraction of the piston plug 725 in the neck bore 20 and of the cap 1032 from about the container neck 419.

The interfitting of the top end of the piston plug 724 within the cap 1032, by socketing the polygonal annular plug flange 727 within the complementary shaped cap socket 76 assures that the piston plug may be easily rotated within the neck bore 20 by the application of rotational force to the cap skirt 1034. The molding operation to form the container from glass, such as puff-blowing, usually provides minute irregularities in the neck bore surface. If the piston plug 725 is molded from rubber and its piston section 726 is held under compression in the outer end of the neck bore 20 for an appreciable storage period the compressed rubber may take a degree of set in the irregular shaping dictated by the minor imperfection irregularities in the neck bore surface, thus tending to develop a minor degree of "freeze" of the plug piston section within the neck bore that initially may resist inward thrust. When the piston plug is tied to the cover cap, the operator can free the piston plug within the neck bore easily by twisting the cap before applying the inward thrust to the latter. Other means of tying the piston plug to the protective cover cap will provide a similar desirable result, such as may be obtained by molding the piston plug and the cap skirt integral with each other. Also, in an embodiment like that proposed in FIGS. 21 and 22 the access hole 36 may be non-uniform in shape, such as polygonal in cross-section, and the piston plug post 75 may be of complementary shape snugly to fit therein for a like purpose.

In the various illustrated embodiments wherein captive means are provided, either by the outward captive means alone or by the supplemental inward captive means, it is assured that the containers remain closed after admixing the ingredients therewithin. When such a device is employed to pre-mix sufficient amounts of the ingredients as to provide a quantity of the admixture for a plurality of dosages to be successively withdrawn, a preferred technique of doing so may involve periodically creating elevated internal pressure prior to the withdrawal of the successive dosages. Withdrawal of a dosage by a hypodermic syringe may be facilitated if the chamber of the syringe is expanded to be filled with air and the latter is then expelled into the container through the hollow needle after it has pierced through the closure or the piston plug thereof by reducing the syringe chamber capacity, so as to elevate the pressure in the container. With the needle remaining pierced through the closure to communication of its bore with the interior of the container, the syringe chamber is again expanded so as to create suction for drawing thereinto the dosage of parenteral liquid. The elevated pressure in the container facilitates this loading of the syringe preparatory to hypodermic injection of its contents. However, the injection of the air into the container for desirably elevating the pressure has a tendency to force the piston plug back out of the container neck bore, i.e., pop it out, which destroys the protectively closed condition of the container for preservation of the remaining dosages therein. The captive means provided by the protective cap of the closure assembly of the present invention assures that this will not occur and that the container will remain closed. If only outward initial position captive means is employed, such elevation of the pressure within the container by injection of the air will retract the piston plug in the neck bore until this outward captive means becomes effective to stop its backward travel. This will reduce to a degree the effectiveness of the pressure elevation, but there will be at least some to facilitate the withdrawal of the dosage into the syringe chamber. However, for this purpose, it is preferred that such outward captive means be supplemented by the inward captive means so that the protective cap will be locked in its inward position of maximum forward thrust as it was employed to thrust the piston plug forward to the "fired" position. In the latter case, since pressure retraction of the piston plug in the neck bore is resisted by the inward captive means, the elevated internal pressure of the container effected by the injection of the air is completely available for facilitating the withdrawal of a dosage into the syringe chamber.

It will thus be seen that the objects set forth above, among those made apparent from the preceding description, are efficiently attained and, since certain changes may be made in the above constructions without departing from the scope of the invention, it is intended that all matter contained in the above description or shown in the accompanying drawings shall be interpreted as illustrative and not in a limiting sense.

It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention herein described, and all statements of the scope of the invention which, as a matter of language, might be said to fall therebetween.

Having described my invention, what I claim as new and desire to secure by Letters Patent is:

1. In an admixing storage container having a substantially filled top liquid compartment, a bottom material compartment, a neck defining the upper end of said top compartment, a piston plug in said neck, said top and bottom compartments being segregated by a gate plug expellable by hydraulic pressure into said bottom compartment through forward movement of said piston plug in said neck, the improvement which comprises:

(a) Screw threads on the upper portion of said neck terminating intermediate its length;

(b) Means on said neck below said screw threads defining a downwardly facing first stop shoulder;

(c) A cap positioned on and telescopically movable over said neck, said cap having means for access to said piston plug by a hypodermic needle;

(d) Internal screw threads on said cap engagable with said screw threads on said neck;

(e) Means on said cap below said cap screw threads defining an upwardly facing second stop shoulder, whereby in the initial outward position of said cap, said first and second stop shoulders are aligned in opposed relation for substantial abutment to resist further removal of said cap, and whereby a forward thrust on said cap causes the internal threads of said cap to engage said threads on said neck to permit threaded advancement of said cap and said piston plug, thereby exerting pressure on liquid in said top compartment to cause expulsion of said gate plug into said bottom compartment to give admixture of the initially segregated ingredients.

2. The admixing storage container of claim 1 in which

at least one of the stop shoulders extends entirely circumferentially around the neck of said container.

References Cited by the Examiner

UNITED STATES PATENTS

1,275,315	8/18	Smith	215—6
1,771,219	7/30	Hein	128—218
2,609,955	9/52	Moore	215—43
2,610,628	9/52	Lockhart	128—272
2,752,060	6/56	Martin	215—43 X
2,869,745	1/59	Lockhart	128—272 X
3,051,343	8/62	Pappas	215—52
3,087,638	4/63	Loper	215—6

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