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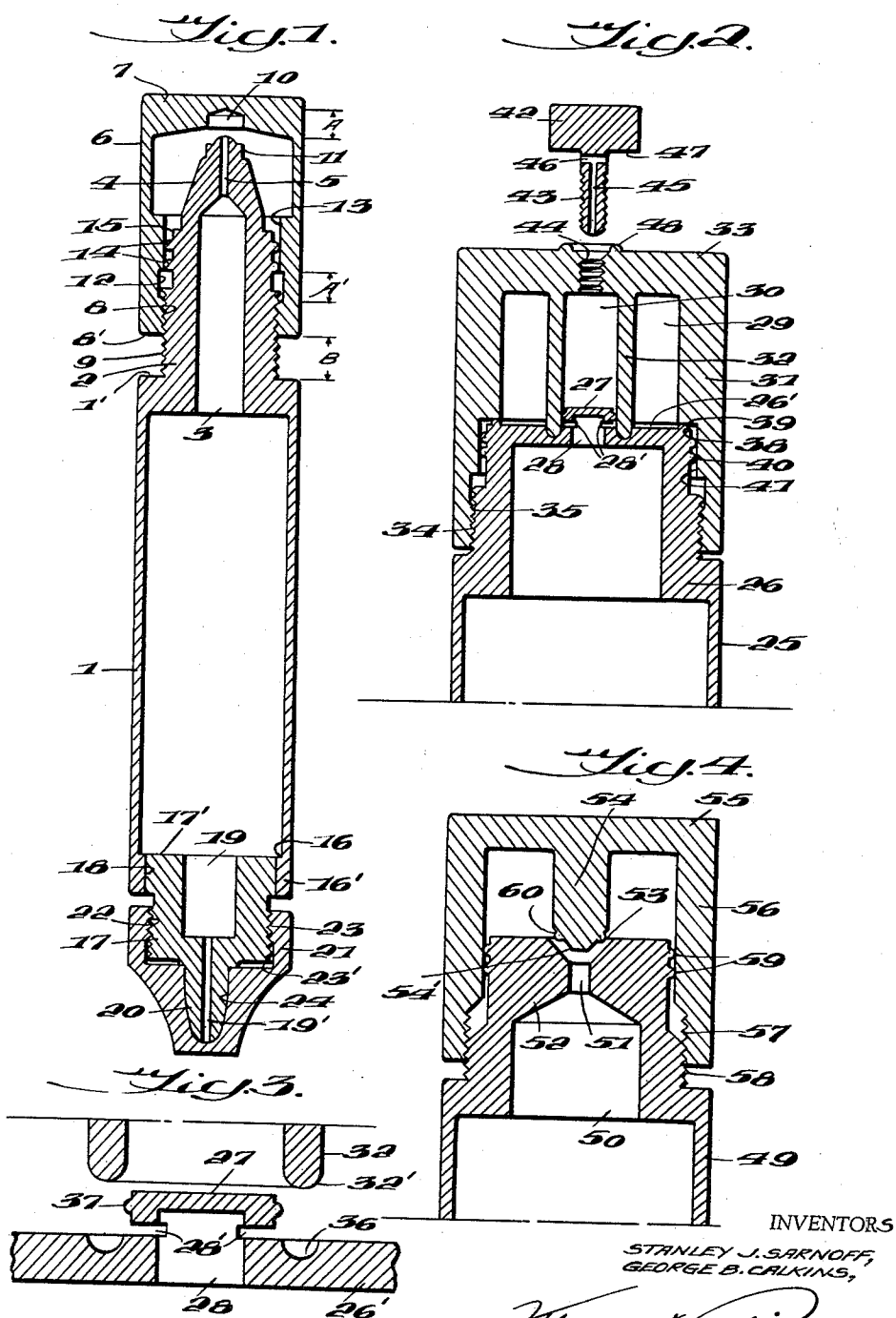
S. J. SARNOFF ET AL

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MEDICAMENT AND DILUENT STORING, MIXING, AND DISPENSING DEVICE

Filed Feb. 25, 1959

3 Sheets-Sheet 1



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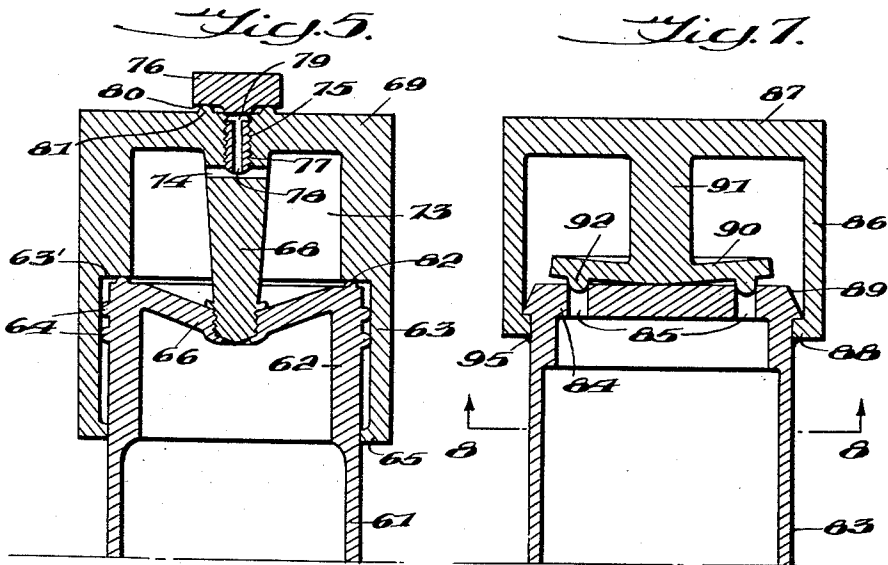
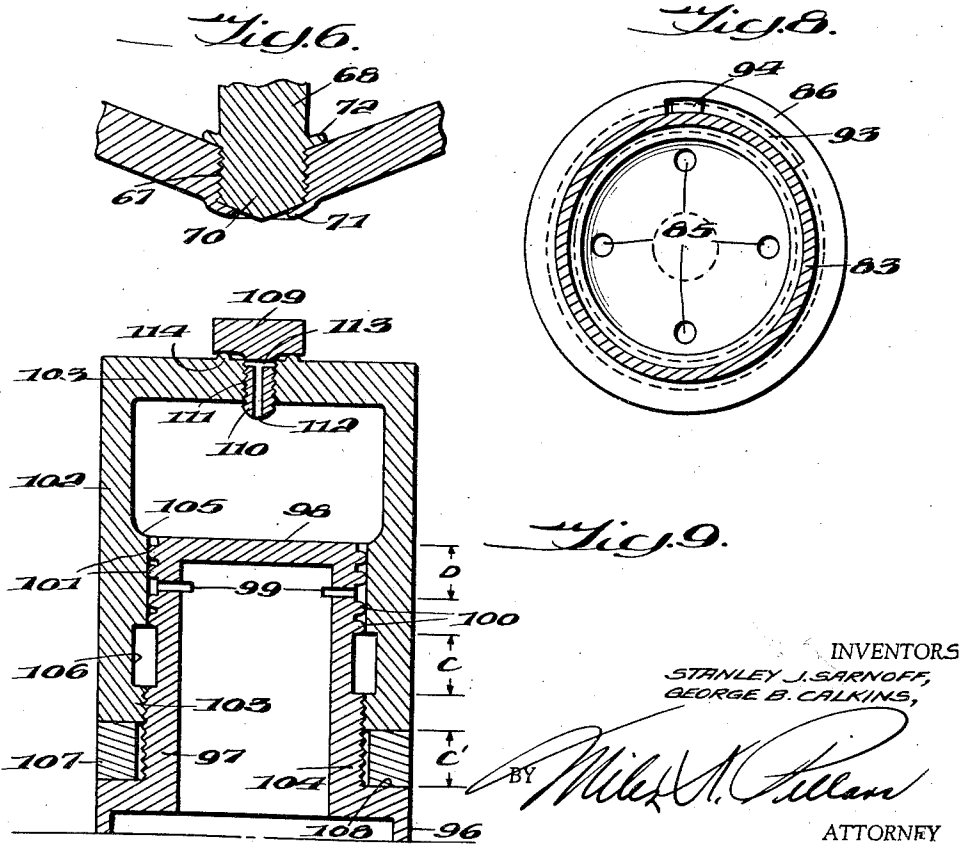
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3 Sheets-Sheet 2



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3 Sheets-Sheet 3

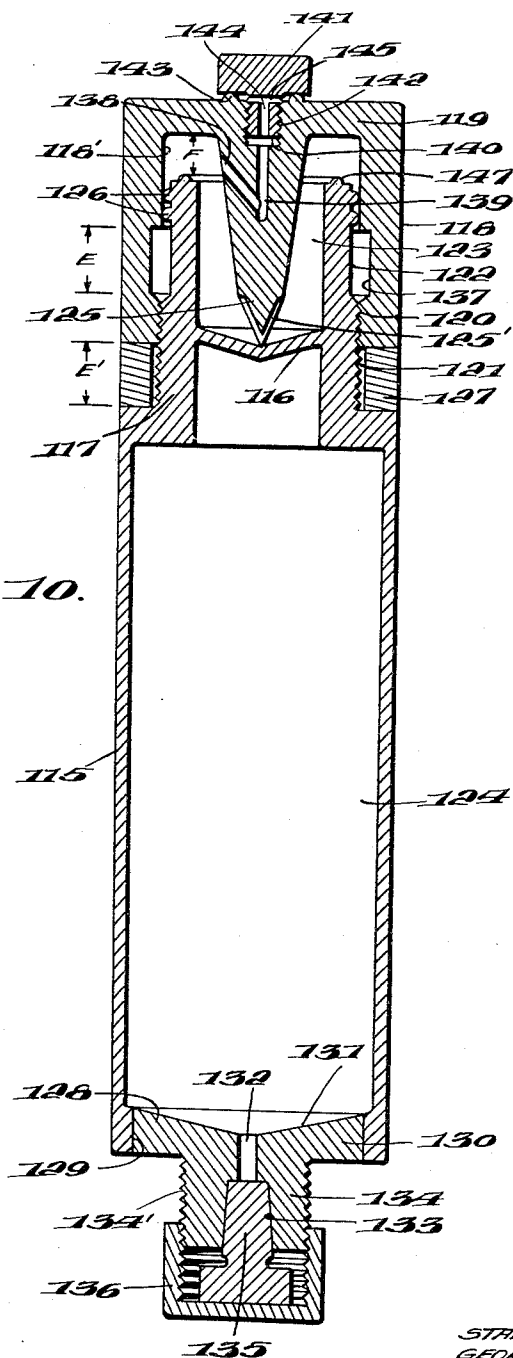


Fig. 10.

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3,070,093

MEDICAMENT AND DILUENT STORING, MIXING, AND DISPENSING DEVICE

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This invention relates to improvements in medicament and diluent storing, mixing, and dispensing devices, and particularly to such devices for storing medicament and diluent in separate chambers within a composite device provided with means for efficiently mixing the medicament and diluent and subsequently dispensing the mixture by either drip or syringe type of action without the need of separate handling of the medicament or diluent and with complete safety against contamination or spilling of the medicament during the use of the device.

In medical technology it has often been found that vaccines and other medicaments require special storage facilities, and that in many cases a dried vaccine or other medicament has superior preservative qualities to the same material in its diluted ready-to-use liquid form. It is not unusual, therefore, to make and store vaccine and medicament in dry form and to mix them with a desired diluent shortly before they are used. This mixing of a dry material with a liquid diluent often entails the use of a plurality of receptacles and, in some instances, a spilling or splattering of vaccine or medicament occurs and may be harmful to the technician preparing the mixture.

It is an object of this invention to provide an improved device for separately storing and for mixing and dispensing a vaccine or medicament and a diluent, which will provide for the ready mixing of the two materials without the possibility of spilling or leaking of the material from the mixing containers during the mixing operation and with a provision for the immediate availability of the mixed materials from the mixing device for use without the need of transferring the mixture to any other container.

It is another object of this invention to provide an improved device for separately storing dry vaccine or medicament and a diluent in predetermined proportions to provide a desired mixture which can be readily prepared within the device and dispensed directly therefrom after mixture of the materials.

A further object of this invention is to provide an improved device for separately storing and for mixing and dispensing a medicament and diluent in predetermined proportions.

Further objects and advantages of this invention will become apparent from the following description referring to the accompanying drawings and the features of novelty which characterize this invention will be pointed out with particularity in the claims appended to and forming a part of this specification.

In the drawings:

FIG. 1 is a longitudinal sectional view through an improved device incorporating an embodiment of this invention for separately storing and for mixing and dispensing medicament and diluent in which the medicament storage chamber is shown as being of the non-vented type and the dispensing end of the device is of the drip type;

FIG. 2 is a longitudinal sectional view of one end of an improved medicament and diluent storing, mixing, and dispensing device which may embody the general features of FIG. 1, and in which the medicament storage chamber and associated end of the diluent chamber are of modified construction providing for a venting of the medicament chamber and also constructed as a dual medicament chamber, whereby two medicaments may be separately stored, if desired;

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FIG. 3 is a longitudinal enlarged fragmentary view of the cooperating sealing and mixing nozzle ends of the medicament and diluent chambers of the device shown in FIG. 2;

FIG. 4 is a longitudinal sectional view of the mixing end of a device, such as that shown in FIGS. 1 and 2, illustrating another arrangement of the sealing and mixing nozzle ends of the medicament and diluent chambers of the device wherein the medicament chamber is shown as being of the unvented type;

FIG. 5 is a longitudinal sectional view of a device embodying the present invention, similar to that shown in FIGS. 1, 2, and 4, provided with a vented type medicament chamber and a positive seal of the material mixing passageway between the medicament and diluent chambers which incorporates a positive securing means, as well as improved lip seals, for assuring against accidental mixture of the materials in the medicament and diluent chambers;

FIG. 6 is a fragmentary enlarged sectional view of the positive securing and sealing arrangement of the device shown in FIG. 5 for sealing the passageway between the medicament and diluent chambers;

FIG. 7 is a sectional fragmentary view of another embodiment of an improved device incorporating the present invention, wherein a simplified securing and mixing orifice sealing construction is illustrated in connection with a medicament chamber and the associated end of a diluent chamber;

FIG. 8 is a sectional view, taken along line 8—8 of FIG. 7, illustrating the relative arrangement and securing lug structure for latching the mixing orifice sealing means between the medicament and diluent chambers of this device;

FIG. 9 is a longitudinal sectional view of the mixing end of a device incorporating the present invention illustrating another type of medicament storage chamber and associated mixing orifice end of a diluent chamber, in which the medicament chamber is shown provided with venting plug means; and

FIG. 10 is a longitudinal sectional view of a device incorporating the present invention for separately storing and for mixing and dispensing medicament and diluent, wherein an imperforate diaphragm separates the medicament chamber from the diluent chamber for storage purposes, and a fluted sharp piercing element is secured to the medicament chamber to provide for piercing of the diaphragm and for the passage of diluent through the diaphragm into and out of the medicament chamber from the diluent chamber, and in which the opposite end of the device is illustrated as provided with a syringe type nozzle connector.

Referring to the drawings, an embodiment of an improved device for separately storing and for mixing and dispensing a medicament or vaccine and a diluent is illustrated in FIG. 1, which incorporates this invention wherein the device is of a type provided with separate medicament and diluent storage chambers which are of a mutually sealing type. In this construction, the diluent chamber comprises a relatively large diluent containing shell 1, preferably substantially cylindrical and also preferably formed of a pliable plastic. One end of the shell 1 is formed with a mixing nozzle 2 extending over the end of the shell and provided with a central mixing supply passageway 3. An end 4 of the mixing nozzle 2 preferably is generally conical in shape and is provided with a passageway 5 extending from the outer end of the supply passageway 3 and terminating in an orifice in the end of the mixing nozzle 2. The outer end of the mixing nozzle 2 is adapted to extend into the medicament chamber to provide for the ready passage of diluent or a mix-

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ture of diluent and medicament between the diluent and medicament chamber.

In order to assure the desired separate storing of medicament and diluent in a single composite device formed by the diluent and medicament chambers, the medicament chamber is formed in this embodiment as a mixing head having a medicament chamber wall 6, preferably of cylindrical form, which is closed at one end by a suitable end wall or cap 7 and terminates in a screw threaded internal shoulder 8. This threaded shoulder 8 on the end of the mixing head is adapted to secure the mixing head to the diluent chamber by screw threaded engagement with a complementary threaded portion 9 of the mixing nozzle 2, and these threaded engaging portions of the mixing head and the diluent chamber nozzle are of such proportions as to provide for securely drawing up the mixing head over the nozzle so as to seal the orifice end of the dispensing passageway 5 in the end of the nozzle. This sealing function of the mixing head is obtained by forming a socket 10 on the inner side of the end wall 7, which is adapted to provide a snug sealing engagement with an outer sealing surface portion 11 on the end of the dispensing nozzle 4.

In order further to assure a good seal between the socket 10 and the sealing surface portion 11 of the nozzle, the shoulder 8 is adapted to be screwed over the threaded portion 9 so as securely to press the end of the nozzle 4 into the socket 10. This is readily provided for by dimensioning the threaded shoulder of the mixing head and the threaded portion of the nozzle so that when the mixing head is screwed outwardly from the nozzle to provide for ready passage of diluent from the diluent chamber into the mixing head, the space A between the orifice end of the mixing nozzle and the end of the socket 10 in the mixing head end wall 7 is less than the distance B between the edge 8' of the threaded shoulder 8 and the adjacent end surface of a shoulder 1' at the end of the threaded portion 9 of the nozzle. In order to provide further for a tight sealing engagement of the end of the nozzle 4 in the socket 10 as the mixing head is screwed down over the nozzle, the inner surface of the medicament chamber wall 6 is formed with a groove 12 extending longitudinally of the medicament chamber from the inner end of the threaded shoulder 8 for a distance A' sufficient to allow the threaded portion 9 to be screwed over the threaded portion 9 of the nozzle to bring the orifice end of the nozzle into tightly pressed engagement in the socket 10.

The engagement of the threaded shoulder 8 of the mixing chamber with the threaded portion 9 of the diluent chamber nozzle forms a seal which assures against accidental spilling of medicament or diluent from the device both during storage and during mixing and dispensing of the medicament and the diluent.

In order further to assure against accidental spilling of material from the device, the mixing head preferably is formed with an inwardly extending shoulder 13 which extends from the end of the groove 12 inwardly of the mixing head to the inner end of the medicament chamber, and a pair of sealing O-rings 14 is formed on the outer surface of an unthreaded shoulder 15 on the nozzle 4 adjacent to the threaded portion 9 thereof of a size adapted to provide a snug sealing engagement with the inner surface of the shoulder 13 on the mixing head. These sealing O-rings preferably are spaced apart so as to provide a leakage material receiving groove therebetween, which further assures against the leakage of material out of the device along the relatively movable securing and sealing surfaces thereof.

This type of medicament and diluent storing and mixing device is adapted to be filled for storage purposes with the medicament and diluent separated and sealed from each other in their respective chambers of the device. When it is desired to utilize the device, the diluent is mixed with the medicament and then is adapted to be

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dispensed by either a drip or syringe dispensing means.

In order to store the medicament and the diluent in their respective chambers of the device and to provide for the most efficient utilization of the space within the device, the desired medicament in powder or other suitable form is placed within the cup-shaped medicament chamber formed by the mixing head walls 6 and 7, and the mixing nozzle 2 of the diluent chamber then is screwed into the threaded shoulder 8 of the mixing head until the end of the nozzle is pressed into snug sealing engagement with the socket 10 in the mixing head end wall 7. This provides a leak-proof seal of the medicament within the medicament chamber of the mixing head. The diluent chamber then is completely filled with diluent to the inner side 16 of a shoulder 16', and the diluent chamber then is closed by a suitable drip or syringe head. This head may be made as the dispenser or may be made as a terminal connection for a drip or syringe dispenser, and is shown in FIG. 1 as a drip type dispenser head. In such a construction, the dispenser head 17 preferably is formed with a sealing flange or shoulder 18 which is adapted to have a snug sealing fit within the inner surface of the shoulder 16' on the end of the diluent chamber wall 1. Such a head 17 is pressed into the end of the diluent chamber flange 16 until the inner surface 17' thereof is substantially flush with the inner side 16 of the diluent chamber shoulder 16', and then preferably is sealed thereto in any suitable manner, as by heat sealing of the engaging surfaces of the shoulders 16' and flange 18. Such a seal can readily be made if the dispensing head 17 is made of suitable plastic material which can be readily heat sealed to the plastic material of which the diluent chamber wall 1' also is made. The dispensing head 17 is formed with an axially extending dispensing passageway 19 which terminates in a relatively small passageway 19' through a drip dispensing nozzle 20, formed on the outer end of the dispensing head, so that material from the device can be dispensed a drop at a time through the small passageway 19' by squeezing the pliable plastic wall 1 of the diluent chamber. In this manner an exact dispensing of the desired quantity of mixed medicament and diluent can be dispensed as desired.

In order to assure against spillage or leakage of the diluent from the device during storage and during mixing of the diluent and medicament, a closure cap 21 formed of any suitable material, such as plastic, is adapted to be arranged over the dispensing nozzle 20 and to seal the dispensing passageway 19' thereof. This closure cap 21 may conveniently take the form of a screw cap having internal threads 22 which are formed and adapted to engage complementary screw threads 23 on a shoulder 23' formed on the end of the dispenser head 17, such that a socket 24 formed in the end of the closure cap 21 can be drawn into tight sealing engagement over the outer surface of the dispensing head nozzle 20. In this manner, the device can be filled with a predetermined amount of medicament and diluent, sealed in separate chambers of the device for storage purposes, with assurance that these materials will not become mixed or contaminated during storage.

When it is desired to use the medicament, the mixing head is screwed outwardly from the diluent chamber to a position corresponding to that shown in FIG. 1, so that the end of the nozzle 4 is free of the sealing socket 10. The device then is held in a position with the mixing head and the nozzle extending downwardly and the sides of the pliable plastic diluent chamber 1 are alternately squeezed and released so as to cause diluent to flow alternately from the diluent chamber into the medicament chamber and back from the medicament chamber into the diluent chamber. In this manner, the medicament and diluent may be thoroughly mixed, while maintaining a complete seal of these materials within the device. After the material has been thoroughly mixed, the

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closure cap 21 can be removed from the dispensing head 17 and the mixed material within the diluent chamber can be dispensed a drop at a time through the small passageway 19' in the drip nozzle 20, thereby providing for a complete separate storage of medicament and diluent, a mixing of the medicament and diluent without the transfer of either of these materials from any separate container for the mixing operation, and a dispensing of the mixed medicament and diluent from the device without any transfer of the material to any separate dispenser. This assures against any possible contamination of the material before its use, and also assures against spilling or splattering of the vaccine or medicament on the personnel preparing or dispensing the material.

In FIGS. 2 and 3, another embodiment of the improved device for separately storing and for mixing and dispensing medicament and a diluent is illustrated. In this construction, as in that shown in FIG. 1, the diluent chamber may be formed of a shell of pliable plastic 25 and may be provided at one end thereof with a suitable dispensing head of the drip or syringe type for dispensing material from the device and for closing one end of the chamber during storage and mixing operations.

The other end of the diluent chamber is formed with a sealing cap portion 26 preferably integral with the shell 25 and provided with a mixing nozzle 27 on the outer end thereof. This mixing nozzle 27 is formed with an axially extending central passageway 28 preferably having a plurality of transversely extending slots or apertures 28' extending from the passageway 28 to the outside of the mixing nozzle 27 to provide for the passage of diluent in and out of the diluent chamber through the mixing nozzle 27 and into a suitable medicament chamber.

In certain instances, it may be desirable to store separately two different medicaments and also to store these two medicaments separately from a common diluent, all three of which are adapted to be mixed and to be dispensed as a mixture. The construction shown in FIGS. 2 and 3 illustrates a type of medicament chamber which may be utilized for such plural medicament storage and mixing purposes. In this construction, the medicament chamber may be formed in a mixing head provided with an outer medicament storing chamber 29 and an inner medicament storing chamber 30 formed by substantially concentric cylindrical walls 31 and 32, respectively, which extend axially from a common end wall 33 of the mixing head.

Separate storage of the medicaments in the chamber 29 and 30, sealed from each other and from the diluent, is assured by providing a secure screw threaded engagement between the mixing head and the diluent chamber and providing additional seals between engaging surfaces of these two members of the device, similar to those of the FIG. 1 construction. These can conveniently be provided by complementary screw threaded shoulders 34 and 35, respectively, adjacent the ends of the medicament chamber wall 31 and the diluent chamber cap portion 26 which are adapted to draw these two elements tightly together and to provide a liquid seal through the threaded engagement of these two members. In order further to assure against the mixing of the plural medicaments with each other, or with the diluent during storage thereof, the cap portion 26 of the diluent chamber is provided with an end wall 26' having a groove 36 formed in the outer surface thereof complementary to the end surface or edge 32' of the central medicament chamber wall 32, so that when the mixing chamber is tightly screwed onto the cap portion 26, the end surface 32' of the wall 32 is pressed into tight sealing engagement with the surface of the groove 36 and prevents the passage of medicament from one medicament chamber into the other and also prevents the passage of diluent from the diluent chamber into the outer medicament chamber.

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The passage of medicament from the inner medicament chamber into and mixture with diluent in the diluent chamber or medicament in the outer medicament chamber also is prevented by sealing of this inner chamber by a special sealing arrangement. This arrangement includes a suitable sealing O-ring 37 formed on the mixing nozzle 27, which is adapted to have a snug sealing engagement with the inner surface of the cylindrical medicament chamber wall 32 when the mixing cap is screwed into storage position, as shown in FIG. 2. In order further to assure against leakage of material during storage, the outer surface of the end wall 26' preferably also is formed with another sealing O-ring 38, which is adapted to engage an adjacent surface of a shoulder 39 formed on the interior of the mixing head wall 31. As shown in FIG. 2, this sealing O-ring 38 is pressed into tight sealing engagement with the surface of the shoulder 39 when the mixing head is drawn tightly into storage position. Further assurance against leakage both during storage and during mixing operations is obtained by providing a pair of sealing O-rings 40 on the outer surface of the sealing cap 26, which are adapted to have a snug sealing fit with the inner surface of a shoulder 41 on the mixing head wall 31 between the shoulder 39 and the screw threaded shoulder 34.

In order to facilitate mixing of the medicaments and the diluent, it often is desirable to provide a substantially leak-proof vent for the various chambers which will provide an effective seal for storage and which can be readily opened when it is desired to mix the medicaments and the diluent. Such a vent can be provided in any of the devices incorporating the present invention, and may take a variety of suitable forms. One of these is illustrated in FIG. 2 and includes the provision of a venting plug 42 having a screw threaded stem 43, which is adapted to have a fluid-tight threaded engagement with a screw threaded aperture 44 formed in the mixing head end wall 33. A relatively small axially extending vent passageway 45 extends into the stem 43 from the outer end thereof and terminates in a transversely extending small vent passageway 46. This transverse passageway is spaced axially of the stem 43 from the inner surface 47 a distance such that, when the venting plug 42 is tightly screwed into the aperture 44, the transverse passage 46 will be effectively sealed, thereby preventing the escape of material through the vent passageways 45 and 46. In order to assure a good seal between the vent plug and the mixing chamber, a sealing O-ring 48 preferably is formed on the outer surface of the mixing head end wall 33 adapted to engage the inner surface 47 of the vent plug and to be pressed into sealing engagement therewith when the vent plug is tightly screwed into its sealing position in the aperture 44.

This construction assures against leakage of any material out of the inner medicament chamber during storage, and provides for a venting of the mixing head by unscrewing the vent cap from the mixing head so that the ends of the transverse passageway 46 are exposed to the atmosphere when it is desired to unscrew the mixing head into mixing position on the diluent chamber. When a vent plug of this type is provided it is advisable to hold the device with the mixing head up, that is, above the diluent chamber so as to prevent leaking or dripping of material from the device through the vent passageways. Mixture of the materials in the device may conveniently be accomplished in the same general manner as in the embodiment shown in FIG. 1 simply by unscrewing the mixing head a short distance from its sealed position, as shown in FIG. 3, until the mixing nozzle 27 is disengaged from the inner end of the inner medicament chamber wall 32. In this position, the mixing nozzle slots 28' are opened into the mixing head and diluent may be forced into the mixing head by simply squeezing the pliable plastic sides of the diluent chamber shell 25 to force diluent through the mixing nozzle and into the medica-

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ment chambers. In order to assure proper mixture of the diluent with the medicaments, the diluent chamber should be as full as possible of diluent, so that it will readily pass from the diluent chamber through the mixing nozzle when the sides of the diluent chamber shell 25 are squeezed. This is particularly important as if the diluent chamber is not full, it would be necessary to squeeze the walls of the shell 25 until all of the air in the diluent chamber had been squeezed out of the chamber before any of the diluent would pass upwardly and out through the mixing nozzle slots 28' into the medicament chambers. A simple repetition of the squeezing and releasing of the pliable sides of the shell 25 will provide for a thorough mixing of the diluent and the two medicaments in the two medicament chambers and a drawing of this mixture into the diluent chamber, from which it can be dispensed by any suitable drip or syringe dispensing head.

FIG. 4 illustrates another embodiment of the present invention similar to that shown in FIGS. 1-3, in which a diluent chamber is formed by a shell having a pliable plastic wall 49 and a mixing nozzle 50 having an axially extending mixing passageway 51 formed in an end wall 52. In this construction, the mixing nozzle passageway is adapted to be sealed for storage purposes by a construction which is essentially the reverse of the sealing socket arrangement shown in FIG. 1. In the present embodiment, the mixing passageway 51 terminates exteriorly in a counter-sunk aperture 53 which forms a socket into which a sealing plug 54 formed on the inside of an end wall 55 of a mixing head 56 is adapted to be pressed into sealing engagement. The mixing head 56 is adapted to be drawn into sealed position over the mixing nozzle 50 by threaded engagement of complementary threaded surfaces 57 and 58 adjacent to the ends of the mixing head and mixing nozzle, respectively. In order to assure against leakage or splashing of material during the mixing of diluent and medicament, a pair of sealing O-rings 59 are formed on the outer surface of the mixing nozzle and are adapted to have a snug sealing engagement with the inner side surface of the mixing head 56.

In a construction such as that illustrated in this figure, medicament is adapted to be placed in the medicament chamber formed in the mixing head 56, and the diluent chamber then is adapted to be screwed into the mixing head until the mixing passageway 51 in the mixing nozzle is sealed by the plug 54. In order to assure a complete sealing of this passageway, the plug 54 preferably is formed with a sealing O-ring 60 on a tapered end surface 54' of the plug, such that when the mixing head is drawn up tightly on the mixing nozzle, the O-ring 60 is securely pressed into tight sealing engagement with the surface of the counter-sunk aperture 53. The procedure for filling the diluent chamber and for mixing diluent and medicament and dispensing the mixture from the device is substantially the same as that for the embodiment shown in FIG. 1.

Another embodiment of this invention is illustrated in FIGS. 5 and 6 in which the dispensing end of the device may take any suitable form, such as that shown in FIG. 1. In this construction, the diluent chamber is provided with a substantially cylindrical pliable side wall 61, preferably of plastic, which terminates in a sealing and mixing end portion 62. This end portion 62 is adapted to extend within a side wall portion 63 of a mixing head and is provided with a pair of sealing O-rings 64, which are arranged with a snug sealing engagement with the inner surface of the mixing-head side wall 63. The mixing-head side wall 63 preferably terminates with an inturned flange 65 on the inner end thereof, which is adapted to be pressed over the O-rings 64 and to have a snug sliding engagement with the outer surface of the cylindrical side walls 61 of the diluent chamber. This inturned flange 65 and the sealing O-ring 64 form a set of liquid seals which prevent the passage of liquid along the adjacent

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surfaces of the walls 61 and 63 of the diluent chamber and the mixing head, respectively. Furthermore, the inturned flange 65 provides a stop with the adjacent O-ring 64, which prevents the complete removal of the mixing head from the diluent chamber unless a very excessive force is applied thereto. This further minimizes the possibility of spilling or splashing of medicament on users of the device.

In this construction, the mixing end portion 62 is formed with an end wall 66 having a central threaded mixing aperture 67 therein. The mixing head is formed with a mixing aperture sealing plug 68, which extends inwardly from an end wall 69 and is formed with a threaded end portion 70 adapted threadedly to engage the mixing aperture 67 to secure the mixing head to the diluent chamber in aperture sealing relationship. A special sealing arrangement is provided for assuring against the passage of materials between the diluent chamber and the medicament chamber within the mixing head. This sealing arrangement includes a sealing lip 71 formed on the diluent chamber side of the end wall 66 of the diluent chamber and extends inwardly of the aperture 67. Another sealing lip 72 is formed on the sealing plug 68 and extends outwardly, such that when the mixing head is drawn into aperture sealing position by screwing the sealing plug 68 tightly into the threaded aperture 67, the end of the sealing plug portion 70 will engage the sealing lip 71 to form a tight liquid seal therewith and the sealing lip 72 will be drawn into tight sealing engagement with the adjacent surface of the end wall 66 and provide another liquid seal therewith.

As in the construction shown in FIG. 2, a suitable vent may be provided between the medicament chamber 73 and atmosphere to facilitate mixing of medicament and diluent during the mixing of materials in the device. This may conveniently take the form of a transversely extending venting passageway 74 formed in the sealing plug 68 which communicates with an outwardly extending threaded passageway 75 into which a vent plug 76 is secured. The vent plug 76 may take the same general form as that shown in FIG. 2, in which a threaded stem 77 is adapted threadedly to engage the threaded passageway 75 and is formed with a small axially extending vent passageway 78, which terminates at one end at the end of the vent plug stem 77 and at the other end in a small transversely extending vent passageway 79 formed in the stem 77 and spaced from the adjacent surface 80 of the vent plug. As in the construction shown in FIG. 2, a sealing O-ring 81 preferably is formed on the outer surface of the end wall 69 and is adapted to engage the adjacent surface 80 of the vent plug to form a seal therewith when the plug is screwed into its vent sealing position, as shown in FIG. 5. Venting of the device can be obtained by merely screwing off the vent plug 76 a short distance, so as to break the seal of the O-ring 81 with the adjacent surface 80 of the vent plug and thereby expose the ends of the transverse vent passageway 79.

The device is adapted to be assembled with medicament and diluent in predetermined quantities. This may easily be done by placing the desired amount of medicament in the medicament chamber 73 and then pressing the diluent chamber into the end of the mixing head and screwing the threaded end portion 70 of the sealing plug 68 into sealing position in the threaded aperture 67 of the diluent chamber end wall 66. A predetermined amount of diluent then is placed within the diluent chamber, preferably filling the chamber, and the dispensing end of the diluent chamber then is closed by a dispensing head in any suitable manner, as explained with reference to FIG. 1. In this manner, the medicament and the diluent can safely be stored in their respective chambers until it is desired to use them. A solution of the diluent and medicament then can readily be made by merely unscrewing the sealing plug portion 70 from the threaded aperture 67 and mixing the contents of the diluent and medicament chambers, as in the pre-

viously described embodiments of this invention. In a construction such as this, it will be found desirable to back off the vent plug 76 to provide for a venting of the medicament chamber prior to its being unscrewed from the diluent chamber, so as to avoid the formation of a vacuum in the medicament chamber. If desired, additional sealing of the device for storage purposes can be obtained by providing another sealing O-ring 82 on the end surface of the diluent chamber and forming the side wall 63 of the mixing head with an inwardly extending shoulder 63' which is adapted to engage the sealing O-ring 81 when the sealing plug 68 is securely screwed into sealing position in the threaded aperture 67. This will further assure against leakage of material from the device during periods when it is kept in storage.

FIGS. 7 and 8 illustrate another embodiment of this invention in which separate diluent and medicament chambers are provided which are secured together in relatively movable and substantially leak-proof relationship to provide the advantages of such construction for separately storing medicament and diluent, and providing for opening a passage between these chambers by relative movement of the chambers to provide for mixing of the medicament and the diluent preparatory to dispensing the mixture from the device.

In this construction, as in the formerly described structures, the diluent chamber is provided with a substantially cylindrical pliable side wall 83 formed of suitable material, such as plastic, and is provided at one end thereof with a suitable closure and dispensing head, which may take the form of either a drip or syringe dispenser. The opposite end of the diluent chamber is provided with an end wall 84 having a plurality of passageways or orifices 85 therethrough, which are adapted to provide communicating passages between the diluent and medicament chambers. As in the previously described constructions, the medicament chamber is formed by a mixing head having a side wall 86 and an end wall or cap 87, which are adapted to form a substantially leak-proof closure around the mixing end of the diluent chamber. The mixing head is secured to the diluent chamber by a simple pressed leak-proof fit. This is provided by forming it with an inwardly extending annular flange 88 on the end of the wall 86 opposite the end wall 87, and the inner diameter of the annular flange 88 is such that the flange forms a snug substantially leak-proof fit with the outer surface of the side wall 83 of the diluent chamber. The mixing head then is secured in position by simply pressing the intumed flange 88 over an outwardly tapered locking flange 89 on the mixing end of the diluent chamber.

In order to provide an easily operable sealed mounting of the mixing head, it is resiliently held in position by a flexible mushroom type closure member. This closure member includes a flexible closure plate 90 formed on the end of a supporting stem 91, which extends axially from the end wall 87 of the mixing head and is of such a length that the closure plate 90 resiliently engages the outer surface of the diluent chamber end wall 85 when the intumed flange 88 of the mixing head has been pressed over the tapered flange 89, into the position shown in FIG. 7. The closure plate 90 preferably is formed with a plurality of relatively shallow sealing protrusions or pimples 92 which are spaced apart and positioned on the outer surface of the closure plate 90 in the same arrangement as the dispensing passageways or orifices 85 in the end wall 84 of the diluent chamber.

In packaging this embodiment of the storing and mixing device, the desired quantity of medicament is placed within the medicament chamber formed by the walls of the mixing head, and the diluent chamber then is pressed into position with the end wall 84 thereof in engagement with the flexible closure plate 90 to a position wherein the tapered flange 89 thereof passes completely through the inwardly extending flange 88 of the mixing head and

forms a retaining latch engagement therewith, as shown in FIG. 7. In order to assure a complete sealing of the medicament chamber from the diluent chamber, the diluent chamber is turned until the protrusions 92 on the closure plate 90 extend into the orifices 85, so as effectively to seal these orifices. The flexing of the closure plate 90 by the pressure of the diluent chamber on this plate tends to hold the protrusions 92 in secure sealing engagement with the sides of the orifices or passageways 85, so as to prevent leakage of material between the diluent chamber and the medicament chamber.

In this construction, it is desirable to have an indication to an operator of the relative position of the mixing head and the diluent chamber, so that an operator will know when the mixing orifices 85 are sealed by the closure plate 90 and when these orifices are open and provide passageways between the medicament and diluent chambers. This can readily be provided by forming a guide slot 93 in the side wall 86 of the mixing head and positioning the mixing head over the diluent chamber so that this guide slot 93 extends over a lug 94 formed on the outer surface of the end wall of the diluent chamber. This arrangement is more clearly shown in the sectional view illustrated in FIG. 8, which shows the diluent chamber lug 94 extending into the guide slot 93 of the mixing head, at one end of the slot. In this position, the lug 94 acts as a stop on the diluent chamber wall which limits the relative turning of the mixing head and the diluent chamber to a position in which the protrusions 92 on the closure plate are in sealing position over the orifices or passageways 85. In order further to assure against leakage during storage of the device, a light heat seal preferably additionally is formed around the outer edge of the flange 88 on the mixing head. Such a seal can readily be formed when both the mixing head and the diluent chamber are formed of plastic by pressing the surface of the diluent chamber wall 83 with a heated instrument, so that a light adhesive bond 95 is formed between the outer surface of the flange 88 and the adjacent surface of the side wall of the diluent chamber. This provides a further effective seal and assures against leakage or contamination of medicament in the medicament chamber during storage of the device.

When it is desired to use the medicament for medicinal purposes, a mixing of the diluent and the medicament can readily be performed by simply turning or twisting the mixing head relative to the diluent chamber in a direction permitted by the slot 93 and suitably shaking the device. Such a relative turning of the mixing head and the diluent chamber again is limited by engagement of the lug 94 with the end of the slot 93, opposite to that shown in FIG. 8. In this position the closure plate 90 is turned relative to the end wall 84 of the diluent chamber such that the protrusions 92 are raised over the outer surface of the end wall 84 out of sealing position with the orifices or passageways 85. This raised position of the protrusions flexes the closure plate 90 away from the adjacent surface of the end wall 84 and provides for an opening of the mixing orifices or passageways 85 to permit the passage of diluent from the diluent chamber into the medicament chamber by simply squeezing the pliable diluent chamber walls 83, so that the diluent and the medicament may be thoroughly mixed. The mixture then can return into the diluent chamber by way of the open passageways 85 to be dispensed from the device through the dispensing head on the opposite end of the diluent chamber.

If desired, the diluent chamber may have an arrow placed on the outer wall thereof adjacent to the lug 94 to indicate the direction in which the diluent chamber should be turned relative to the mixing head in order to open the mixing passageways 85. Such a turning of the diluent chamber relative to the mixing head will break the light heat seal bond 95, but this will not affect the leak-proof seal formed between the flanges 88 and 89 as the turning

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of the diluent chamber relative to the mixing head will cause these two flanges to be more intimately biased into sealing engagement with each other due to the added pressure exerted therebetween by the flexing of the closure plate 90 as the protrusions 92 are raised when they are disengaged from their positions over the passageways 85 and slide over the outer adjacent surface of the diluent chamber end wall 84. This simplified construction includes all of the advantages of the embodiments of the present invention shown in FIGS. 1 through 6 and minimizes the number of relatively movable sealing and contacting surfaces, thereby minimizing the possible sources of leakage and also eliminates the need for screw threaded securing means. The entire device preferably is formed of pliable plastic material which provides the desired flexibility and resiliency to the various co-acting parts of the device.

FIG. 9 illustrates another embodiment incorporating this invention for a device for separately storing and for mixing and dispensing a medicament and a diluent. This device is provided with a diluent chamber having a substantially cylindrical pliable side wall 96 provided at one end thereof with a suitable dispensing head of the drip or syringe type and formed at the other end thereof with a mixing end portion in the form of a substantially cylindrical section 97, closed at the outer end thereof by an end wall 98. Mixing orifices are formed in the sides of the cylindrical section 97 adjacent to the end wall 98 in the form of slots 99 on both sides of which a pair of sealing O-rings 100 and 101 are formed. A mixing head is secured over the mixing end of the diluent chamber and is formed with a side wall 102 and an end wall 103, which provide a medicament chamber over the end of the end wall 98 of the diluent chamber.

This mixing head is adapted to be secured to the diluent chamber by an inturned threaded flange 103, which threadedly engages a threaded section 104 of the outer surface of the cylindrical section 97 of the diluent chamber. The mixing head side wall 102 also is formed with an inwardly extending shoulder 105, which is adapted to cooperate with the two pairs of sealing O-rings 100 and 101 to provide a snug sliding seal therewith.

In order to provide for effectively sealing the device and for the most efficient utilization of the space within the operable parts the sealing shoulder 105 is spaced axially from the inturned threaded flange 103 by a groove 106 having an axial extent C which is greater than the distance D of the inner edges of the slots 99 from the outer surface of the end wall 88. This allows for the easy screwing of the inturned flange 103 over the threaded section 104 to a position wherein the slots 99 are exposed into the medicament chamber. In order to assure proper spacing of the mixing head and the mixing end portion of the diluent chamber, a removable split snap-on safety ring 107 is arranged around the threaded section 104 between the end of the mixing head flange 103 and an adjacent shoulder 108 on the end of the diluent chamber. This safety ring is formed of a width C' substantially equal to the axial extent C of the slot 106, so that, when the mixing head is drawn up on the threaded section 104 of the diluent chamber, the sealing O-rings 100 and 101 will effectively engage the inner surface of the flange 105 and seal the mixing slots 99 against all possible leakage of diluent from the diluent chamber into the medicament chamber or out of the device. This arrangement also assures that the mixing slots 99 will be fully exposed to permit passage of diluent into the medicament chamber for mixing of the diluent and medicament by simply removing the split safety ring 107 and screwing the diluent chamber further into the mixing head until the end of the threaded flange 103 engages the shoulder 108 of the diluent chamber.

In order to facilitate the relative movement of the diluent chamber and the mixing head to provide for a mixture of the diluent and the medicament, the mixing head also preferably is provided with a venting arrangement similar

to that shown in FIGS. 2 and 5. In this arrangement, a vent plug 109 may be conveniently formed with a stem 110, which threadedly engages a passageway 111 in the end wall 103 of the mixing head. The vent plug is formed with an axially extending relatively small vent passageway 112 which is open at the end of the stem 110 and terminates inwardly of the plug in a relatively small transversely extending vent passageway 113, which is spaced slightly from the adjacent under surface of the vent plug 109. The end wall 103 of the mixing head preferably is formed with a sealing O-ring 114, which is adapted to be engaged by the adjacent under surface of the vent plug 109 when the plug is screwed tightly into the end wall 103, thus providing a leak-proof seal of the vent passageways.

In most instances it will be found desirable to vent the medicament chamber before screwing the mixing head over the threaded section 104 for mixing the diluent and the medicament. This can easily be done by simply backing off the vent plug a turn or two, so as to expose the ends of the transverse passageway 113 in order to facilitate screwing the mixing head down over the threaded section 104 of the diluent chamber cylindrical section 97. As in the other constructions provided with a venting arrangement, the diluent chamber should be substantially completely filled with diluent and the mixing of the diluent with the medicament should be done with the mixing head held above the diluent chamber in order to avoid spilling or leaking of diluent out of the device through the vent passageways, the diluent being squeezed out of the diluent chamber into the medicament chamber in the mixing head by simply squeezing the sides of the pliable side wall 96 of the diluent chamber. This construction provides a substantially more sturdy device than some of the previously described arrangements, and may be preferable for certain materials and certain uses of such a device.

A still further embodiment of the present invention is illustrated in FIG. 10, wherein a device is shown for separately storing and for mixing and dispensing medicament and a diluent, which includes a diluent chamber having a pliable side wall 115 formed of any suitable material, such as plastic, and adapted to be closed at one end thereof by a suitable dispensing head of the drip or syringe-connector type, and closed at the opposite end thereof by a closure end wall or diaphragm 116 extending across a mixing end portion 117. In this construction, a mixing head is secured over the mixing end portion of the diluent chamber. This mixing head includes a substantially cylindrical side wall 118, which is closed at one end thereof by an end wall 119 and is provided with a threaded inwardly extending shoulder 120 on the end thereof opposite the wall 119 adapted threadedly to engage a threaded portion 121 of a shoulder on the outer surface of the end portion 117. In order to provide for the ready threaded engagement between the shoulder 120 and the threaded portion 121, the outer surface 122 of the portion 117 is formed on a smaller diameter than that of the threaded shoulder 120. The mixing head forms a cup-shaped closure, which extends over the mixing end portion 117 and together therewith forms a medicament chamber 123.

In order to provide for passage of diluent from the diluent chamber 124 into the medicament chamber 123, a piercing or cutting blade 125, having a fluted end 125', extends from the end wall 119 of the mixing head towards the open end thereof. The sharp piercing end of this cutting blade is adapted to rest against the adjacent surface of the end wall or diaphragm 116 of the mixing end portion 117 of the diluent chamber when the threaded shoulder 120 of the mixing head is screwed onto the threaded portion 121 such that a pair of sealing O-rings 126 adjacent the outer end of the mixing end portion 117 snugly and sealingly engage the inner surface 118' of a shoulder on the side wall 118 of the mixing head. With such a construction, medicament or vaccine in a dry form may be placed in the medicament chamber 123 and the mixing head then can be screwed onto the threaded portion

121 of the mixing end portion 117 of the diluent chamber. In order to assure the proper positioning of the piercing blade 125 against the end wall or diaphragm 116 for storage of the device, a removable split snap-on safety ring 127 is placed around the lower end of the threaded portion 121.

In assembling this embodiment of the device, the medicament or vaccine first is placed in the medicament chamber 123 and the mixing head is screwed into the position shown in FIG. 10. The diluent chamber 124 then is filled with diluent and a dispensing head 128 is fitted snugly within an inwardly extending sealing shoulder 129 formed on the end of the diluent chamber wall 115 away from the medicament chamber 123. In the illustrated construction, the dispensing head is shown as a syringe type dispensing head attachment, although a drip type head, such as that shown in FIG. 1, could also be used for closing this end of the diluent chamber, if desired.

The illustrated dispensing head includes an end wall 130 which forms a tight pressed fit within the sealing shoulder 129 and is formed with a sloping inner surface 131 to provide for a better drainage of liquid from the diluent chamber 124 through a dispensing passage 132, which extends through the wall 130 and opens into an enlarged passage 133 formed in a syringe-connecting collar 134. The passage 133 is adapted to be sealed by a suitable end plug 135, which can be held in sealing position in the passage 133 in any convenient manner, as by a cap 136 arranged over the plug 135 and adapted to have a threaded engagement with the outer threaded surface 134' of the collar 134. If desired, such a cap and the plug 135 may be made as an integral unit. In order further to assure against leakage of diluent from the diluent chamber 124 past the sealing shoulder 129, the dispensing head 128 also preferably is formed of a suitable plastic and the sealing shoulder 129 is heat sealed to the adjacent surface of the dispensing head 128, after the diluent chamber has been filled and the dispensing head pressed into position within the sealing shoulder 129.

In order to prepare the medicament and the diluent for use as a liquid mixture thereof, the spacing snap-ring 127 is removed and the mixing head is screwed down over the threaded portion 121, so that the fluted piercing end 125' of the blade 125 pierces the end wall or diaphragm 116 to permit diluent to flow from the diluent chamber 124 through flutes in the fluted end 125' of the piercing blade, and into the medicament chamber 123. In order to facilitate the piercing of the end wall 116 by the blade 125 and to facilitate screwing down of the mixing head, a groove 137 is formed along the inner surface of the mixing head wall 118 which has a width E substantially equal to the width E' of the spacing safety ring 127. This groove 137 permits the mixing head to be screwed down over the threaded portion 121 without interference with the threads of this portion.

In order further to facilitate the screwing down of the mixing head, a venting arrangement preferably is provided which includes a relatively small venting passage 138 which extends through the blade 125 and terminates in another relatively small venting passage 139 extending substantially axially through the blade 125 and terminating in a threaded vent plug socket 140. For normal storage conditions, a vent plug 141, having a threaded stem 142, threadedly engages the vent plug socket 140 and is drawn up tightly against a sealing O-ring 143 on the outer surface of the mixing head end wall 119, so as to prevent the escape of material from the medicament chamber through the vent passages. This vent plug 141 is formed with an axially extending vent passage 144, which is open to the inner end of the stem 142 and terminates inwardly in a transversely extending vent passage 145. The transverse vent passage 145 is axially

spaced a small distance from the inner surface 146 of the vent plug, so that when the vent plug 141 is drawn up tightly in the threaded socket 140 the transverse vent passage 145 is securely sealed against leakage by the engagement of the sealing O-ring 143 with the adjacent surface 146 of the vent plug.

When it is desired to screw the mixing head downwardly over the threaded portion 121 in order to pierce the end wall 116 by the blade 125, the vent plug 141 should be backed off one or two turns so as to break the seal between the O-ring 143 and the adjacent surface 146 of the vent plug, thereby to permit the escape of air from within the medicament chamber 123 through the venting passages. In order to assure against spillage and leakage of material from the device during mixing of diluent with medicament, the outer edge of the mixing end portion 117 preferably is formed with a sealing O-ring 147 and the axial length of the mixing end portion 117 relative to the length of the side wall 118 of the mixing head preferably is made such that the axial distance F between the inner surface of the mixing head end wall 119 and the sealing O-ring 147 is slightly less than the width E' of the spacing ring 127. Thus, when the mixing head is fully screwed down over the threaded portion 121 the sealing O-ring 147 will have a snug sealing engagement with the inner surface of the end wall 119 and will assure against leakage of material out of the medicament chamber 123 between the adjacent side walls of the mixing head and the mixing end portion.

With this construction, the procedure of mixing diluent with medicament should be performed with the mixing head held above the diluent chamber, so that liquid will not be spilled or splashed out of the vent passages through the vent plug 141 as the side wall 115 of the diluent chamber is squeezed to force the diluent from the diluent chamber 124 into the medicament chamber 123. In most instances in a vented construction of the present type, it will be found preferable to screw down the vent plug 141 tightly into sealing engagement with the O-ring 143 when it is desired to dispense the mixed liquid from the device through the dispensing head 128. If desired, the vent plug 141 need not thus be sealed, but in such a case care must be exercised to hold the vent plug end of the device uppermost to prevent squirting of material outwardly through the vent passages when the side 115 of the diluent chamber is squeezed during the dispensing operation. Even this precaution, however, may be found undesirable, as liquid may remain in the medicament chamber 123 and may be forced outwardly through the vent passages during such a dispensing operation. It will be found that this embodiment of the present invention is particularly useful where it is desired to provide an absolutely solid wall seal between the medicament and the diluent for storage purposes.

While particular embodiments of this invention have been illustrated and described, modifications thereof will occur to those skilled in the art. It is to be understood, therefore, that all arrangements and constructions within the spirit and scope of this invention are intended to be covered in the appended claims forming a part of this application.

We claim:

1. A device for separately storing and for mixing and dispensing a medicament and a diluent including a medicament chamber, a diluent chamber, means including an integral wall of said diluent chamber forming a closure between said chambers having a passage therethrough adapted to communicate with both of said chambers, means securing said chambers together in a relatively movable relationship, means for sealing said passage and providing for opening of said passage and the mixing of the medicament and diluent and for the passage of the medicament into the diluent chamber through said passage, said diluent chamber having a dispensing aperture therein removed from said medicament chamber, means other

than said securing means for sealing relatively movable adjacent surfaces on said two chambers to provide an externally substantially leakproof seal therebetween, removable closure means over said dispensing aperture, and said diluent chamber having walls formed of resilient de-

formable material for exerting pressure on the mixture of medicament and diluent whereby such mixture may be dispensed through said dispensing aperture.

2. A device for separately storing and for mixing and dispensing medicament and a diluent including a dry medicament chamber, a diluent chamber, means including a wall forming a closure between said chambers and having a passage therethrough extending between said chambers, means securing said chambers together in relatively movable relationship and providing for sealing and opening said passage by relative movement between said chambers, means other than said securing means for sealing relatively movable adjacent surfaces on said two chambers to provide an externally substantially leakproof seal therebetween, said diluent chamber having a dispensing aperture therein removed from said medicament chamber, removable closure means over said dispensing aperture, said medicament chamber having a vent aperture, means for closing said vent aperture, and said diluent chamber having walls formed of resilient deformable material for varying the pressure therein whereby material may be expelled therefrom and aspirated thereinto to provide for mixing of medicament and diluent and for dispensing the mixture thereof through said dispensing aperture when open.

3. A device for separately storing and for mixing and dispensing a medicament and a diluent including a medicament chamber, a diluent chamber having walls formed of resilient deformable material, means for securing said chambers together to form a unit thereof with said chambers in relatively movable relationship, means other than said securing means for sealing relatively movable adjacent surfaces on said two chambers to provide an externally substantially leakproof seal therebetween, means including an integral wall of said diluent chamber for providing a passage between said chambers by relative movement thereof whereby the medicament and the diluent may be mixed and the medicament may pass into the diluent chamber, and said diluent chamber having a drop-let form dispensing portion removed from said medicament chamber.

4. A device for separately storing and for mixing and dispensing a medicament and a diluent including a medicament chamber, a separate diluent chamber movable relative to said medicament chamber, means for mounting said chambers together to form a unit thereof with said chambers in relatively movable relationship, said mounting means including complementary screw-threaded engaging portions with relatively movable sealing means adjacent to said threaded portions, means including said threaded portions for providing a passage between said chambers by relative movement thereof whereby the medicament and the diluent may be mixed and the medicament may pass into the diluent chamber, said mounting means additionally including displacement latching and chamber movement limiting means with sealing means against external leakage, said diluent chamber having a dispensing aperture therein removed from said medicament chamber, removable closure means over said dispensing aperture, and said diluent chamber having walls formed of resilient deformable material for exerting pressure on the mixture of medicament and diluent therein whereby such mixture may be dispensed through said dispensing aperture.

5. A device for separately storing and for mixing and

dispensing a medicament and a diluent including a medicament chamber, a separate diluent chamber movable relative to said medicament chamber, means for mounting said chambers together to form a unit thereof with said chambers in relatively movable relationship, said mounting means including complementary screw-threaded engaging portions with relatively movable sealing means adjacent to said threaded portions, means including said threaded portions for providing a passage between said chambers by relative movement thereof whereby the medicament and the diluent may be mixed and the medicament may pass into the diluent chamber, said mounting means additionally including displacement latching and chamber movement limiting means with sealing means against external leakage, and said diluent chamber having a dispensing portion therein removed from said medicament chamber.

6. A device for separately storing and for mixing and dispensing a medicament and a diluent including a container forming a diluent chamber and having walls of resilient deformable material, a medicament chamber having walls overlaying in part said diluent chamber walls, means including another wall integral with said diluent chamber forming a closure between said chambers, a passage through one of said diluent chamber walls adapted to communicate with said medicament chamber when open, passage sealing means, means securing said chambers together in relatively movable relationship whereby said passage sealing means may be operated to passage sealing and opening positions by relative movement of said chambers to provide for mixing of the medicament and the diluent and for the passage of the medicament into the diluent chamber through said passage, said diluent chamber having a dispensing means removed from said medicament chamber, and means other than said securing means for sealing relatively movable adjacent surfaces on said two chambers to provide an externally substantially leakproof seal therebetween.

7. A device for separately storing and for mixing and dispensing a medicament and a diluent including a container forming a diluent chamber and having walls of resilient deformable material, a medicament chamber adjacent to said diluent chamber and having walls overlaying in part said diluent chamber walls, means including another wall integral with said diluent chamber forming a closure between said chambers, a passage through said diluent chamber walls overlaid by said medicament chamber wall and adapted to communicate with said medicament chamber when open, passage sealing means, means securing said chambers together in relatively movable relationship whereby said passage sealing means may be operated to passage sealing and opening positions by relative movement of said chambers to provide for mixing of the medicament and the diluent and for the passage of the medicament into the diluent chamber through said passage, said diluent chamber having a dispensing means removed from said medicament chamber, and means other than said securing means for sealing relatively movable adjacent surfaces on said two chambers to provide an externally substantially leakproof seal therebetween.

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