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# Home Use Sharps Disposal

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# UltiMed Company Overview

- Corporate office located in St. Paul, Minnesota
- Manufacturer of insulin syringes & pen needles sold throughout the U.S. & Canada
- Some of UltiMed's unique characteristics:
  - Smaller than the dominant sharps manufacturer (Becton Dickenson), which has over 85% market share
  - Privately owned
  - Shareholders are deeply concerned about the downstream consequences caused by accidental needle sticks
  - Has been actively involved with promoting safe disposal of sharps waste in the U.S & Canada
  - The only sharps manufacturer who bundles a sharps container with needles



# Types of Home Use Sharps Devices

Insulin Syringe



Pen Needle (attach to pen injector)



Lancet (attach to lancing device)





# Who Uses Sharps at Home?

- Insulin Syringes - nearly 100% used by diabetics
- Pen Needles - over 90% used by diabetics with remaining used for growing list of conditions & diseases such as multiple sclerosis, arthritis, HIV, osteoporosis, cancer, hepatitis and growth hormones.
- Lancets - over 90% used by diabetics

**Diabetics generate well over 90% of home generated sharps waste**





# U.S. Diabetes Fast Facts

Diabetes affects 25.8 million people of all ages

8.3% of the U.S. population

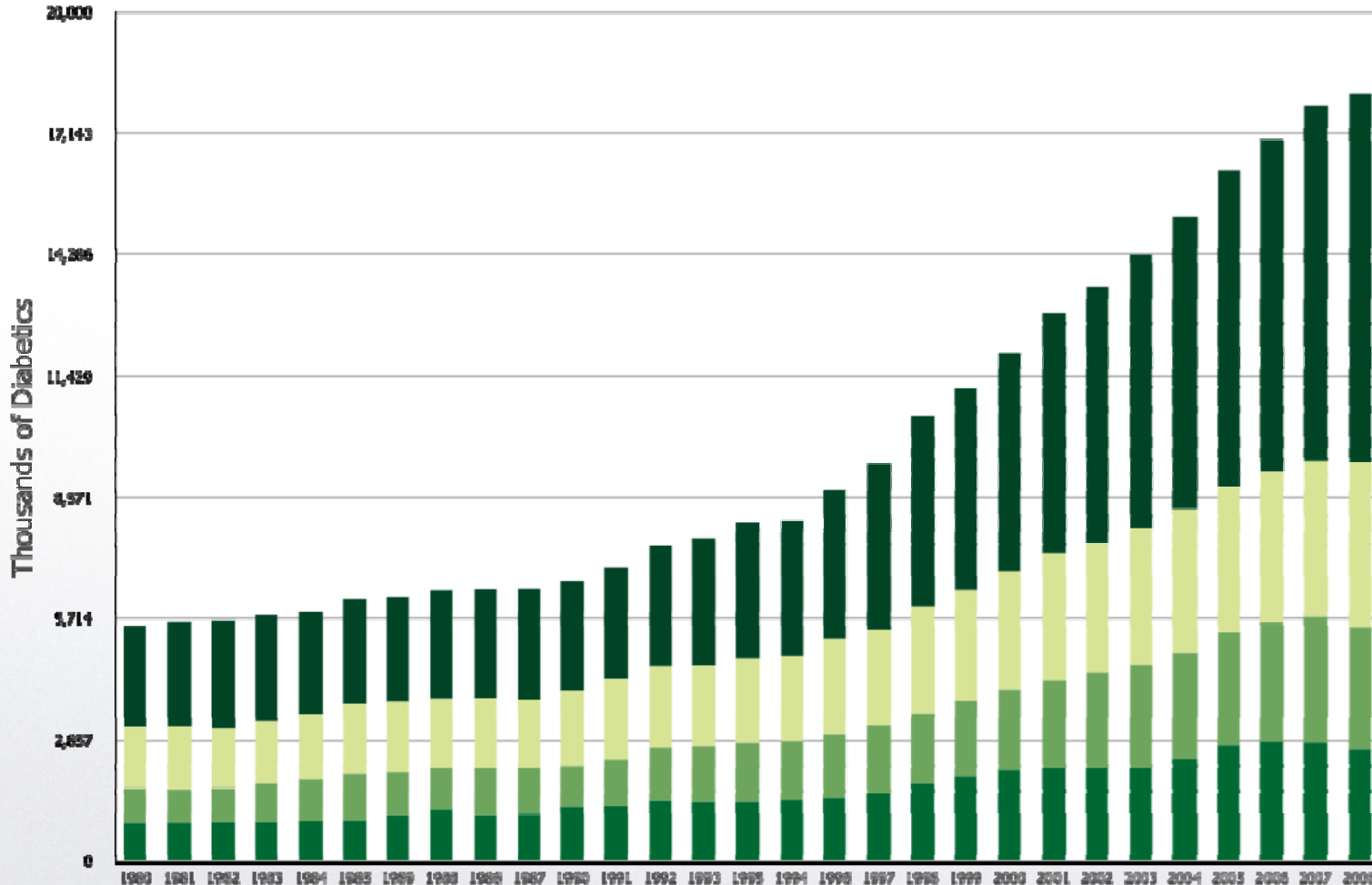
Diagnosed 18.8 million people

- 10.9 million or 27.0% of residents > 65 years had diabetes in 2010.
- 215,000 < 20 years had diabetes in the in 2010.
- 1.9 million people > 20 years were newly diagnosed with diabetes in 2010.
- 35% of adults > 20 years had pre-diabetes (50% of adults > 65 years).
- Its estimated 79 million American adults > 20 years are pre-diabetic.
- Diabetes is the leading cause of kidney failure, non-traumatic lower limb amputations, and new cases of blindness among adults.
- Diabetes is a major cause of heart disease and stroke.
- Diabetes is the seventh leading cause of death in the U.S.



# U.S. Diabetes Growth

## Diabetes Prevalence Amongst Age Groups



### Diabetes Prevalence Amongst Age Groups

A CDC report estimates that the number of Americans with diabetes will range from 1 in 3 to 1 in 5 by 2050.

### Who Is At Risk?

Risk factors for type 2 diabetes include older age, obesity, family history, having diabetes while pregnant, a sedentary lifestyle, and race/ethnicity, according to the report.

African-Americans, Hispanics, American Indians/Alaskan Natives, and some Asian-Americans and Pacific Islanders are at higher risk for the disease, the CDC said.

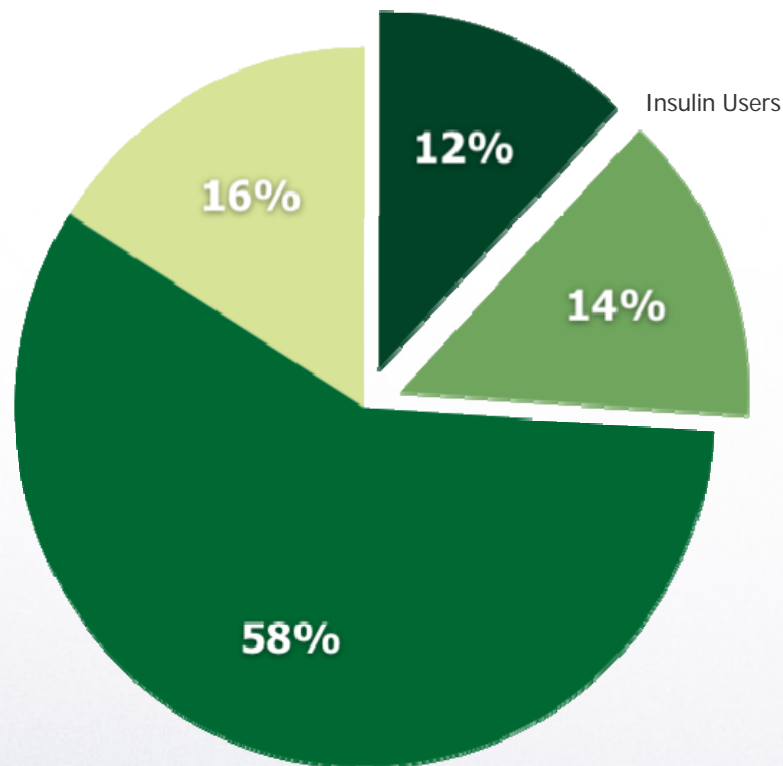
### Highest to Lowest as of 2008

- 45 to 64 Years Old
- 65 to 74 Years Old
- 75 Years Old and Up
- 0 to 44 Years Old

Source - Centers for Disease Control and Prevention.



# U.S. Treatment of Diabetes



- 2,256,000 Insulin Only
- 2,632,000 Insulin + Oral Medication
- 10,904,000 Oral Medication
- 3,008,000 No Medication

Total - 18.8 million

- Among adults diagnosed with diabetes:
  - 12% take insulin only
  - 14% take both insulin and oral medication
  - 58% take oral medication only
  - 16% do not take insulin or oral medication
- ~ 30% of the diabetes population is currently on insulin therapy, representing 4.9 million people.



# The Problem

- 93% of diabetics throw their used, unprotected sharps into the trash
- 3% flush them down the toilet
- 4% put them in a puncture-resistant container
- A needle stick injury can cost upwards of \$3,000 for follow-up care

**Only a small percentage of the 4% disposed of in a puncture resistant container are delivered to an approved medical collection site**





# Three Elements of a Successful Disposal Program

1. Sharps Containers
2. Convenient Collection Sites
  - Hospitals, physician offices, health clinics, fire departments, point-of-purchase sites, and medical waste facilities
  - Mail-back
3. No Cost to the Sharps User





# Sharps Containers

All sharps containers are deemed by the FDA to be Class II Medical Devices, thus must pass pre-market certification (FDA 510-k) to be sold in the U.S.

Three types of home use sharps containers:

Non mail-back (example: *BD Home Sharps Container* which hold 70-100 insulin syringes or 300 pen needles)

Optional mail-back which has either non-mail back or purchase mail-back option (example: *Sharps Compliance Complete Needle Collection & Disposal System*. Holds 70-100 insulin syringes or 300 pen needles)

Dual-purpose packaging which convert into sharps containers (example: *UltiCare* and various private label brands which hold more than 100 syringes or pen needles)



# Federal, State & Local Programs

- Federal EPA Guidelines

- State Programs

- No states have legislation which address the three elements of a successful sharps disposal program

- Local Programs

- There are local programs in the U.S. which incorporate the three elements of a successful program.



# State Program California SB 1305

## What does SB 1305 (2006) say?

- Prohibits sharps waste from being deposited in the same waste stream as normal household garbage.
- Home-generated sharps waste shall be transported in an approved sharps container to authorized household hazardous waste facilities

## SB 1305 (2006) does not:

- Give any agency the authority to collect fees
- Supply sharps containers at no cost
- Facilitate point-of-purchase return
- Have a means of funding for mail-back return
- Contain penalties for non-compliance



# Local Program Sioux Falls

- Metrics of Sioux Falls, South Dakota Sharps Disposal Program
  - Landfill audits indicate the Sioux Falls landfill had the lowest percentage of sharps waste in the U.S.
  - Based on the sales of sharps in the Sioux Falls market and the number of free sharps containers, its estimated there is over a 90% compliance rate.
  - The Sioux Falls program started with one local chain, Lewis Drug.
  - Many studies indicate that diabetics are the most valued customers for pharmacies.
  - In order to compete, other local pharmacies in the Sioux Falls area started a similar program.
  - The success of the Sioux Falls program was “market driven”.



# U.S. Summary

With the exception of some local programs, the U.S. is lagging behind many other developed countries in the proper disposal of used sharps devices.



# Why is the U.S Lagging Behind?

## Political pressure from:

- Sharps manufacturers
- Pharmacies
- Pharmaceuticals (when threatened to pay for the disposal of sharps)
- Medical waste disposal companies (mail-back vs. route pick-up)

## Default Positions:

- Educational programs and instructions for sharps users

There is no empirical evidence that any existing education programs have the high measurable compliance rates of programs which incorporate the three elements of a successful sharps disposal program.

- Needle clipping devices

The consensus is needle clippers also require sharps containers for safe disposal



# Canada

In 1990's, in an effort to attract diabetic customers, nearly all Canadian pharmacies began offering free sharps containers and free sharps disposal. Thus Canada has a history of a "market driven" solution to the sharps waste issue.

Stericycle supplies sharps containers and has pickup for used sharps and unused medications at nearly every pharmacy and vet clinic in Canada.

- *Steripacs* for sharps
- *Buckets* for unused medications

Shoppers Drug Mart

Extended Producer Responsibility

- Stewardship Ontario
- Manitoba and British Columbia