



## PharmaJet Overview & Value

- *History of Needle-Free Jet Injection*
- *Stratis® Needle-free Injector*
- *Why Stratis for Flu Shots?*
- *Regulatory Clearances*
- *Clinical Study Results*
- *User Experience Data – Patients*
- *User Experience Data – Healthcare Providers*
- *Cost/Benefit Comparison*
- *Education & Training Tools*
- *Value of Needle-free for*
  - Pharmacies
  - Public Health Providers
  - Healthcare Institutions

*Colorado Children's Immunization Coalition Meeting – January 15, 2015*



# PharmaJet<sup>®</sup>

*Needle-Free Injection<sup>™</sup>*



Needle-Free Jet Injection  
History for Immunization

# Needle-Free Jet Injection - Clinical Efficacy & Safety

60 Years of Published Evidence across ~250 studies

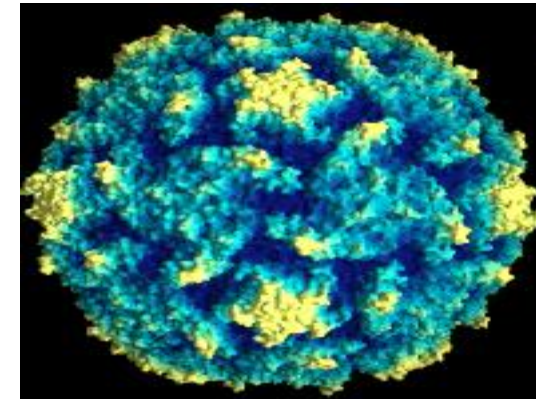
- Delivery by jet injection is equal to or better than needle & syringe as evaluated by immune response
- Increased local site reactions with jet injection; well tolerated

## Inactivated Vaccines:

- Botulism
- Cholera
- DTP
- Hepatitis A
- Hepatitis B
- **Influenza**
- Japanese encephalitis
- Meningococcal A, C
- Polio
- Tetanus
- Typhoid
- Novel: DNA, Peptide

## Live Vaccines:

- BCG
- Measles
- Mumps
- MMR
- Measles-Smallpox
- Rubella
- Smallpox
- Yellow Fever



Vaccines, 5th ed. Philadelphia, PA: Saunders (Elsevier); 2008;1357-1392 [ISBN 978 1 4160 3611 1].  
Weniger BG, Papania MJ. Alternative Vaccine Delivery Methods [Chapter 61]. In: Plotkin SA, Orenstein WA, Offit PA, eds.

## ❖ **Centers for Disease Control and Prevention – CDC 2011 General Recommendations on Immunizations**

*"Jet injectors prevent needle-stick injuries to health-care providers and can overcome improper, unsterile reuse and other drawbacks of needles and syringes. Immune responses generated by jet injectors against both attenuated and inactivated viral and bacterial antigens are usually equivalent to, and occasionally greater than, immune responses induced by needle injection."*

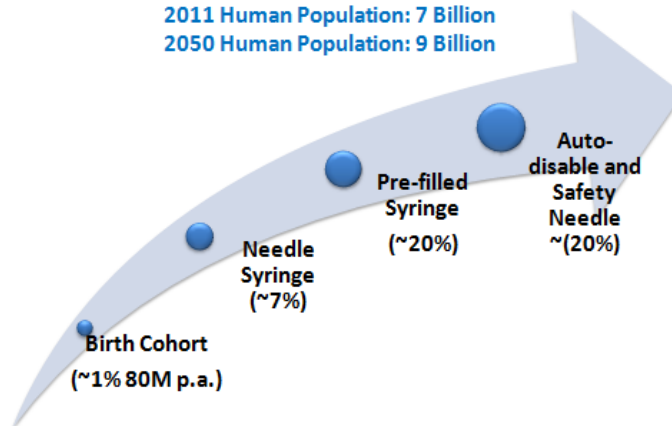
# Focus: Vaccines

- Large growing global market
- Immunization:
  - Core requirement for healthy populations
  - Least expensive form of preventative healthcare
- Many vaccines under development providing large future opportunity
- Needle stick, re-use, and pass along disease create need for “safe injection”
- 50% of needle syringe use considered “unsafe” by the WHO<sup>3</sup>
- Simple training, safe, consistent delivery

## Significant Vaccine Market Annual Growth

~\$20B Annual Vaccine Market; ~15% Growth

2011 Human Population: 7 Billion  
2050 Human Population: 9 Billion



## ~2.5 Billion Syringes Used For Yearly Vaccinations

50% of needle syringe use considered “unsafe” by the WHO



Definitions: WHO – World Health Organization, ROW – Rest of World

# Needle-Free is not new, but PharmaJet is the “new” Needle-Free



Safe. Easy. No Needle.



PharmaJet's needle-free, single use, auto-disable, spring powered injector passes WHO PQS testing and evaluation, becoming the first needle-free jet injection device cleared for UNICEF procurement for 101 countries (January 2013)

**PharmaJet**<sup>®</sup>



# Global Demonstrated Benefit & Acceptance



Needle-free  
Flu Shot  
May be covered by

Cambodia Mass Immunization Program:

<http://www.youtube.com/watch?v=8lZ4pbNzUP0>

Cambodia Healthcare Worker Interview:

<http://www.youtube.com/watch?v=ExwEdTX-udI>

Kuwait National Immunization Week

[http://www.youtube.com/watch?v=p\\_LUGjrQUpk&feature=youtu.be](http://www.youtube.com/watch?v=p_LUGjrQUpk&feature=youtu.be)

<http://www.youtube.com/watch?v=oKwnAZSw6N0>



Global experiences in clinics, pharmacies, and mass immunization venues have confirmed care-giver and patient utility and preference vs. needle-syringe delivery (usually ~90% prefer PharmaJet)

**PharmaJet**

# PharmaJet<sup>®</sup>

*Needle-Free Injection<sup>™</sup>*



PharmaJet's Immunization Device

# Stratis<sup>®</sup> Needle-free Jet Injector

- Safe, easy, cost effective and a better experience for patient and caregiver.



## 0.5mL Intramuscular (IM) Injections





# Stratis Workflow – Fast & Intuitive

1. Prepare Injector



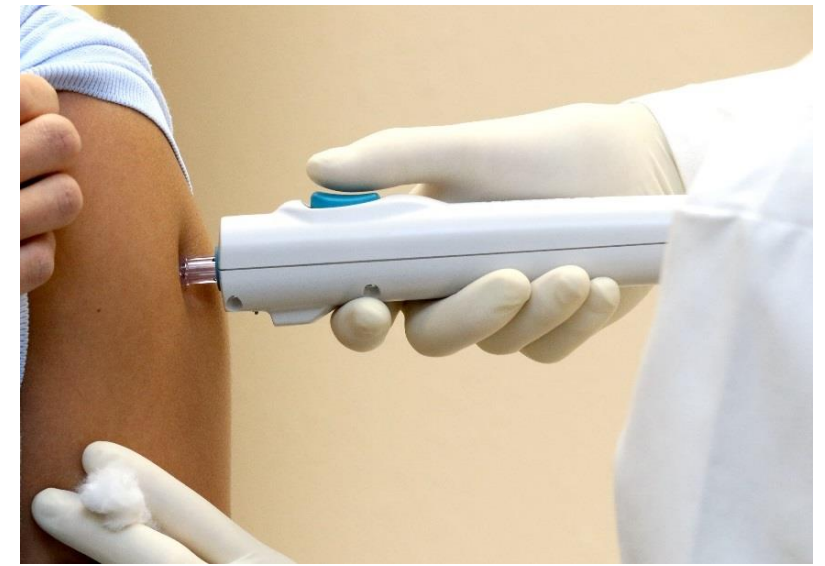
2. Fill Syringe



3. Load Injector



4. Give Injection



- Time competitive with needle-syringe

<http://pharmajet.com/product/>

Majority of users are self-trained within 20 minutes

# Regulatory Clearances

*FDA News – August 19<sup>th</sup>, 2014*



World Health Organization



World Health Organization



Federal Ministry of Health,  
Islamic Republic of Pakistan



وزارة الصحة  
Ministry of Health



Republic of Turkey  
Ministry of Health



MINISTRY OF  
FOOD AND DRUG SAFETY



ANVISA

and others...



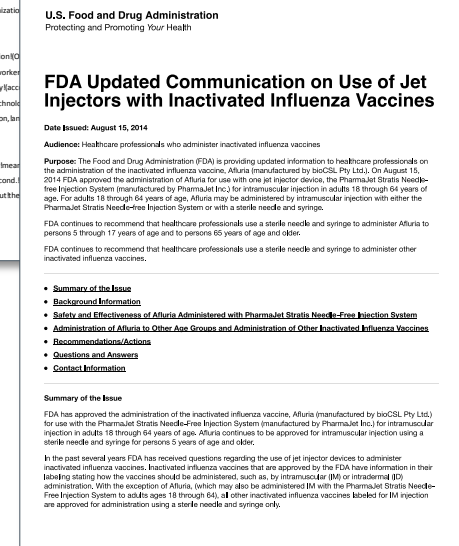
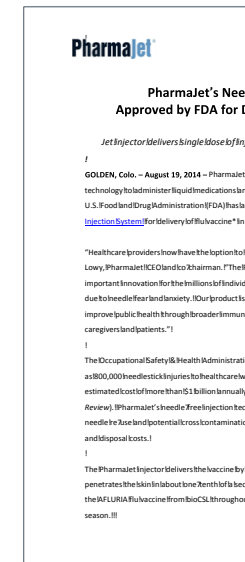
Center for Devices and  
Biological Health

PharmaJet's Class II medical devices allow for delivery of "various medications and vaccines" under their 510k marketing clearances.

## PharmaJet Quality

### Rigorous Testing Standards

- FDA-registered and listed
- Good Manufacturing Practices
- WHO/PQS Certified
- ISO 13485 QMS compliant
- ISO 21649 Needle Free WW Standard compliant
- ISO 10993, ISO 11737 Single Use, Sterility compliant
- ISO 11607, ISO 11135, and ISO 11137



# PharmaJet<sup>®</sup>

*Needle-Free Injection™*



Needle-Free Market Drivers

# The Economic Burden (and Incentive) Around Influenza

## **An Easy Money Saver: the Flu Shot**

Pharmacies Offer Them; Health Law Makes Them Affordable

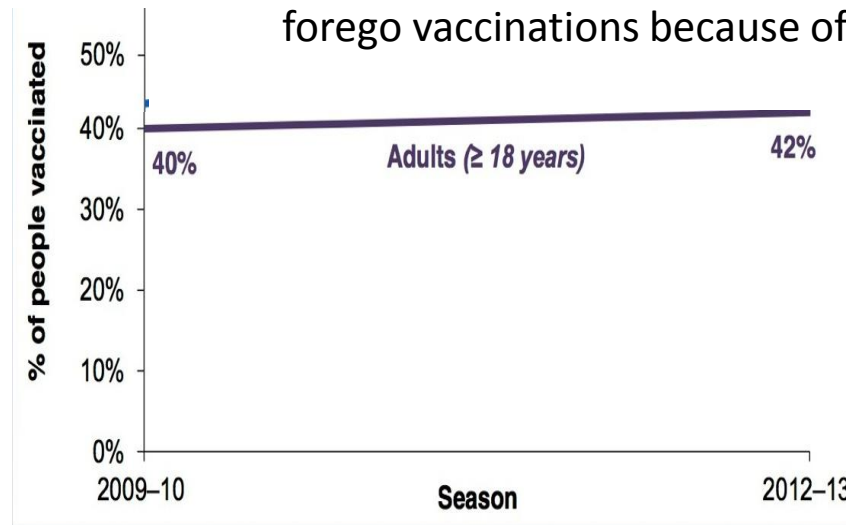


The CDC estimates that the flu costs the U.S. more than \$87 billion a year and results in 17 million lost workdays.



# Why Needle-free Jet Injectors for Flu Shots?

- ✧ **CDC:** Recommends all US citizens over 6 months old receive an annual influenza vaccination.
- ✧ **HHS:** *Healthy People 2020* campaign that includes the goal of 70% flu immunization compliance by the year 2020. (90% for HCP)
- ✧ **However, flu immunization rates hover at ~40% for the past 5 years.<sup>1</sup>**
  - The US adult population needs improved delivery options, better access and better convenience for receiving a flu shot.
  - **Needles are a barrier to immunization;** Up to 24% of people forego vaccinations because of an aversion to needle injections.<sup>2</sup>



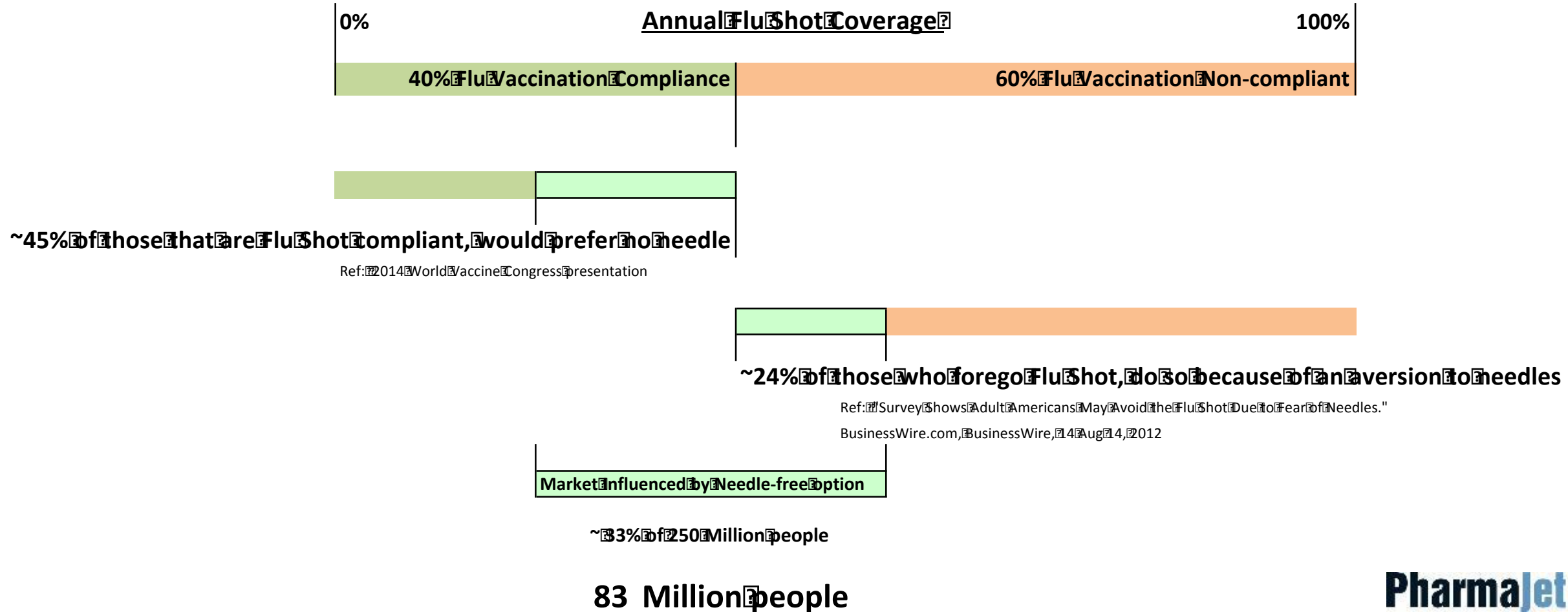
Compliance	
'13-'14 Flu Season (est.)	
18-49:	24.7%
50-64:	39.2%
>65:	60.4%

- ✧ **PharmaJet can help facilitate increased immunization coverage.**

**PharmaJet**<sup>®</sup>

# Market Opportunity

PharmaJet provides a safe, effective, needle-free option for retail pharmacies focused on attracting new customers



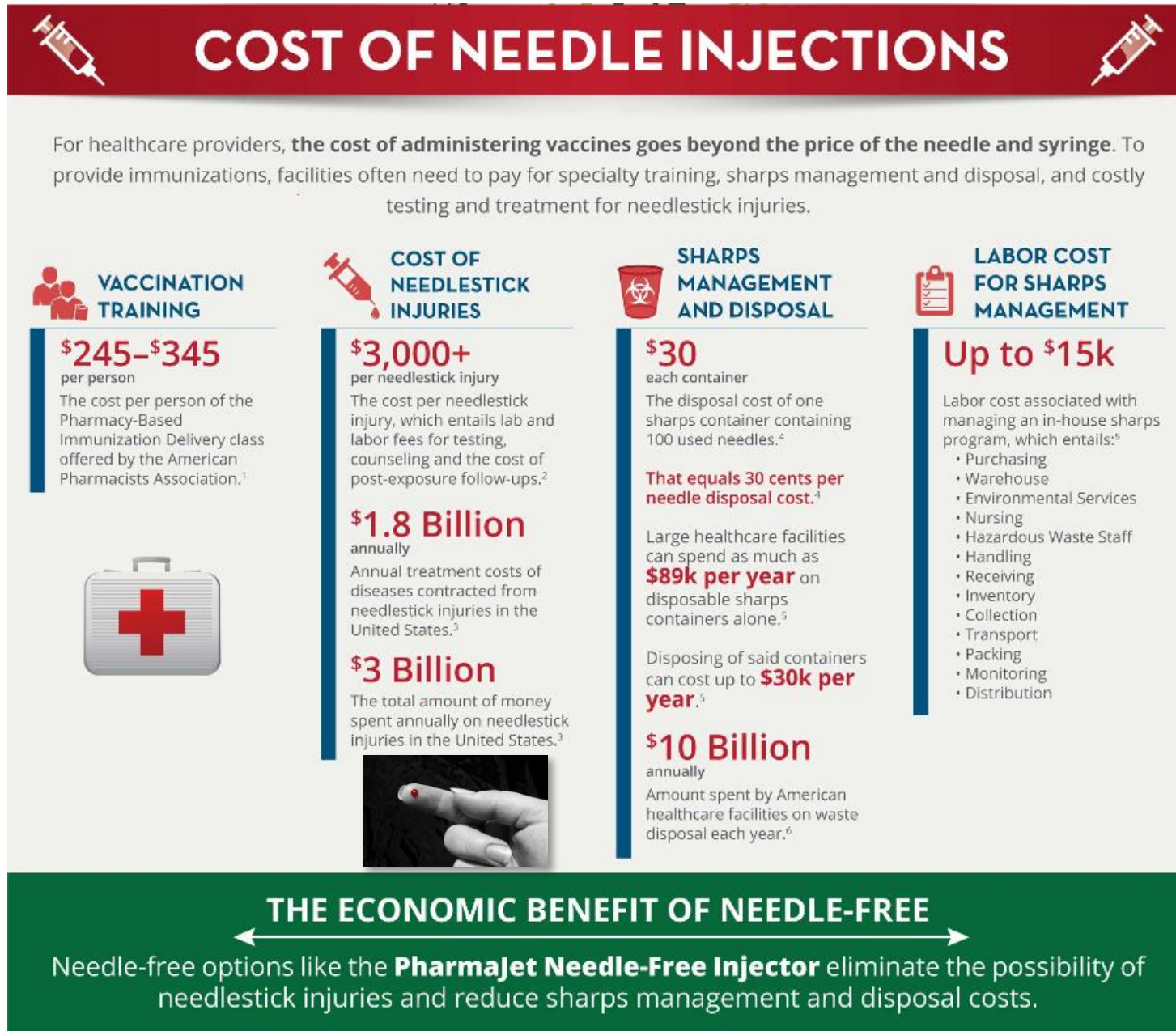
**PharmaJet**

# Value Proposition – Saves Lives and Money



- No needle!
- Single use
- Auto-disabling
- Inherent dose accuracy
- Simple waste disposal (syringe has no needle)
- Minimal dead space

# Value Proposition – Saves Lives and Money





# Value Proposition – Saves Lives and Money

Needlestick injuries can expose healthcare workers to over **20 different bloodborne pathogens** including **HIV, hepatitis B virus, and/or hepatitis C virus**.

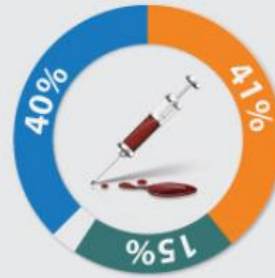


**CDC estimates rates of seroconversion are:**  
(development of detectable specific antibodies to microorganisms in the blood serum as a result of injection)

**HepB- 6%-30%** after needlestick injuries

**HepC- 1.8%**

**HIV- 0.3%**



**When do needlestick injuries occur?**

**40%** of injuries occur after use and before disposal of sharp devices

**41%** of injuries occur during the use of sharp devices on patients

**15%** of injuries occur during or after disposal



- Safe for you and me
- Intuitive
- Cost effective



## Who are exposed to needlestick injuries?

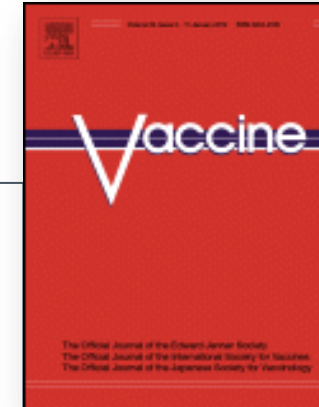


16,17,18,19,20,21,22

# Needles Contribute to Immunization Non-Compliance

*Survey of the prevalence of immunization non-compliance due to needle fears in children and adults.*

Taddio, A *et al*  
Vaccine, Vol. 30:32, July 2012; 4807-4812



- “Needle fears are a barrier to immunization in children and adults.”
- Surveyed: 1907 children and parents
  - 24% of adults and 63% of children report a fear of needles.
  - Close to 10% of all candidates are non-compliant due to needles.

# PharmaJet<sup>®</sup>

*Needle-Free Injection<sup>™</sup>*

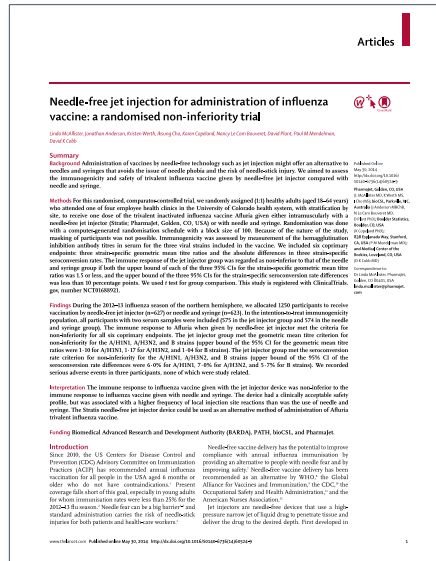


Influenza Example:  
Patient Experience & Clinical Confirmation





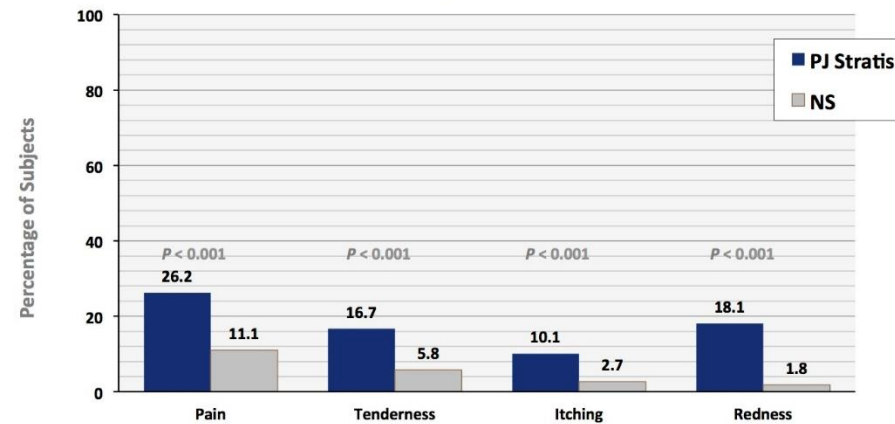
# Clinical Study Results



## Safety

### Immediate Local Reactions ( $\leq 30$ min)

Higher frequency with PJ *Stratis*, but mild in intensity and well-tolerated



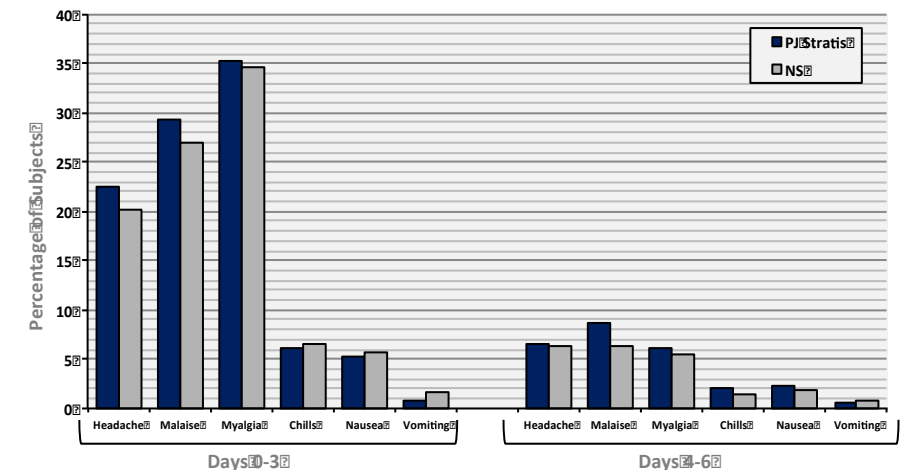
- No bruising noted in either group
- No difference in swelling between groups (both  $< 1.0\%$ )
- All local reactions were only Grade 1 or 2

## Safety

### Solicited Systemic Adverse Events

Days 0-3 and Days 4-6

Systemic adverse events were comparable between groups





# Clinical Study Results

## **ACIP** Advisory Committee on Immunization Practices



- Podium Presentation at October ACIP meeting - October 29, 2014
- 30 minute update on PharmaJet Injector use with bioCSL *Afluria*
- JIFI study results; regulatory status; user preference data
- Very positive visibility and credibility for PharmaJet non-inferiority and safety

*“PharmaJet can help facilitate broader immunization compliance”*

**PharmaJet**<sup>®</sup>

# User Experience Data – Patient Feedback



**FLU SHOT DAY**  
OCT. 9, 2014 | 9:00 AM - 3:00 PM  
Madison Plaza Lobby

**FLUZILLA**  
WILL YOU BE READY?

For all UTHSC students, employees, post-docs, residents, & retirees.  
Produced by: University Health Services, College of Pharmacy, the Office of Student Life, APhA-ASP, & the SGAEC.

Featuring traditional Fluvirion trivalent & needleless, jet injector Afluria vaccine.



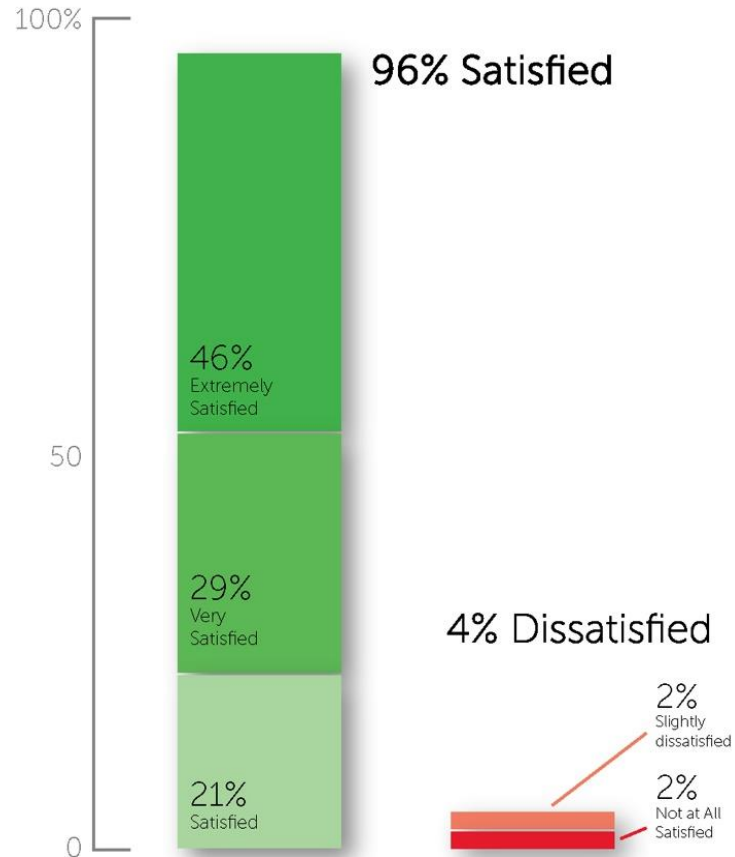




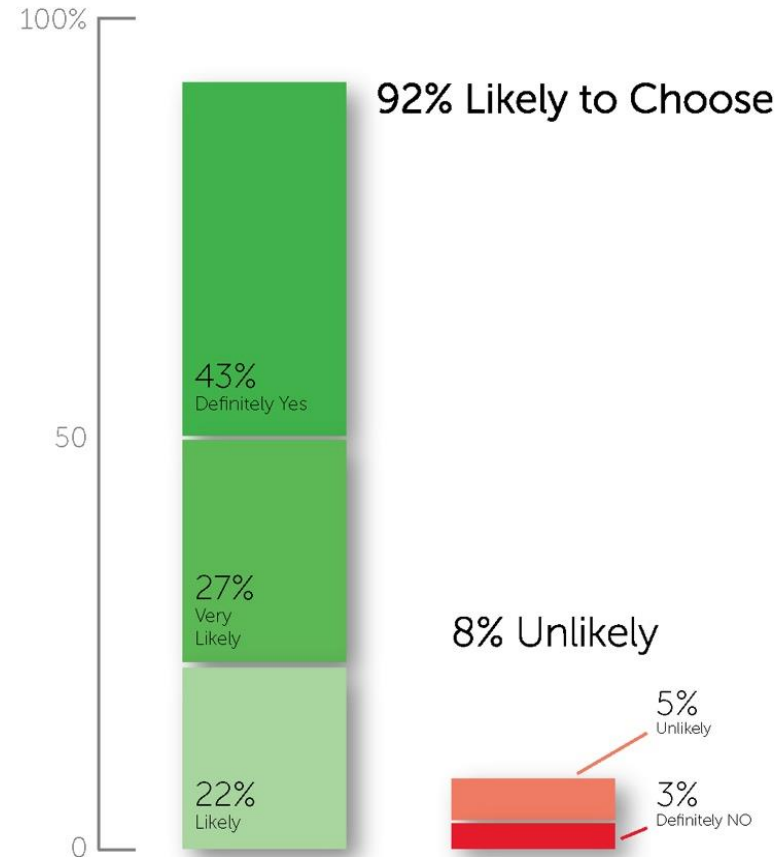
## 500 Needle-free injections – Oct. 2014



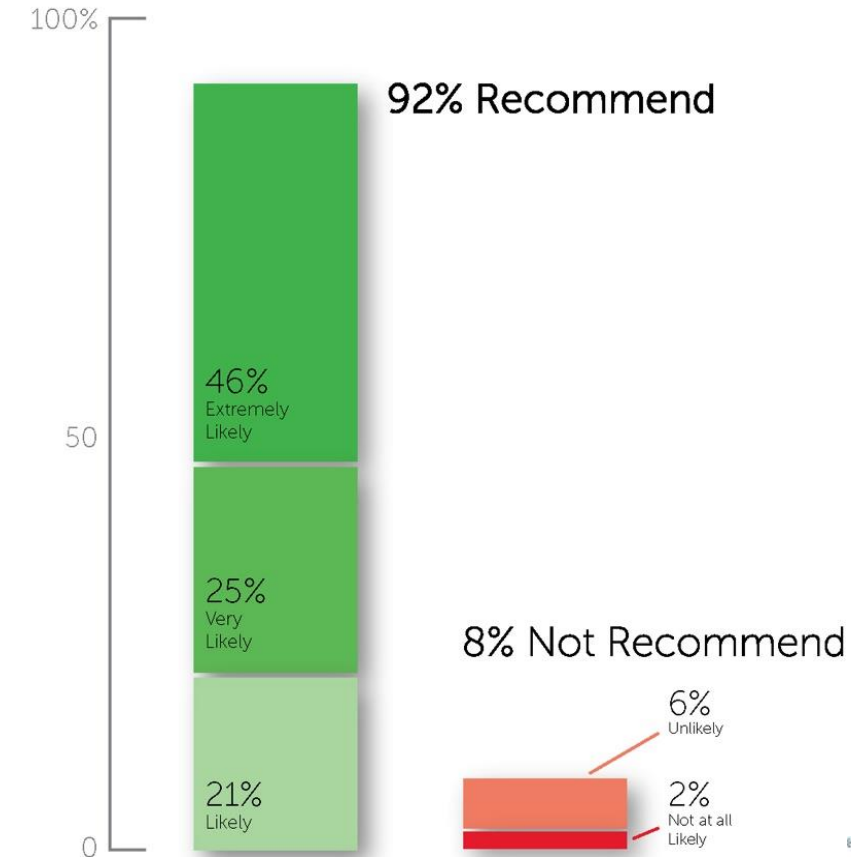
How satisfied were you with today's Needle-Free Flu Shot?



For next year's flu vaccination, will you choose to receive your flu shot with a Needle-Free Injection?

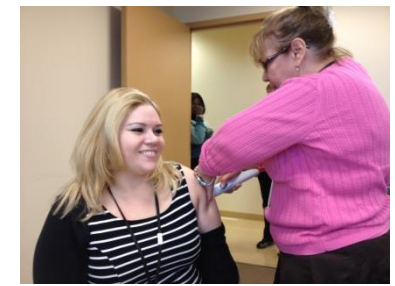


How likely are you to recommend a Needle-Free Flu Shot to family and friends?

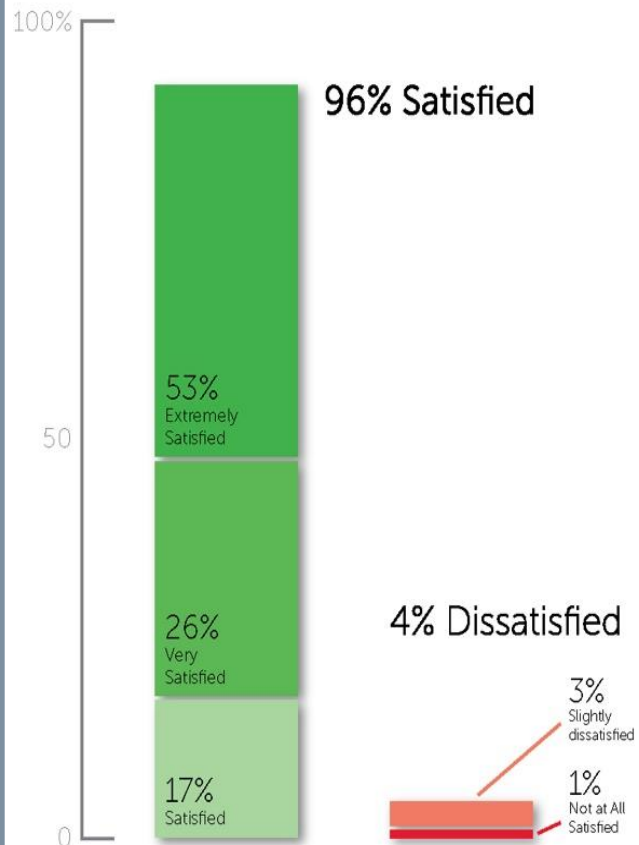


University of TN Health Science Center - Flu Shot Day - 2014

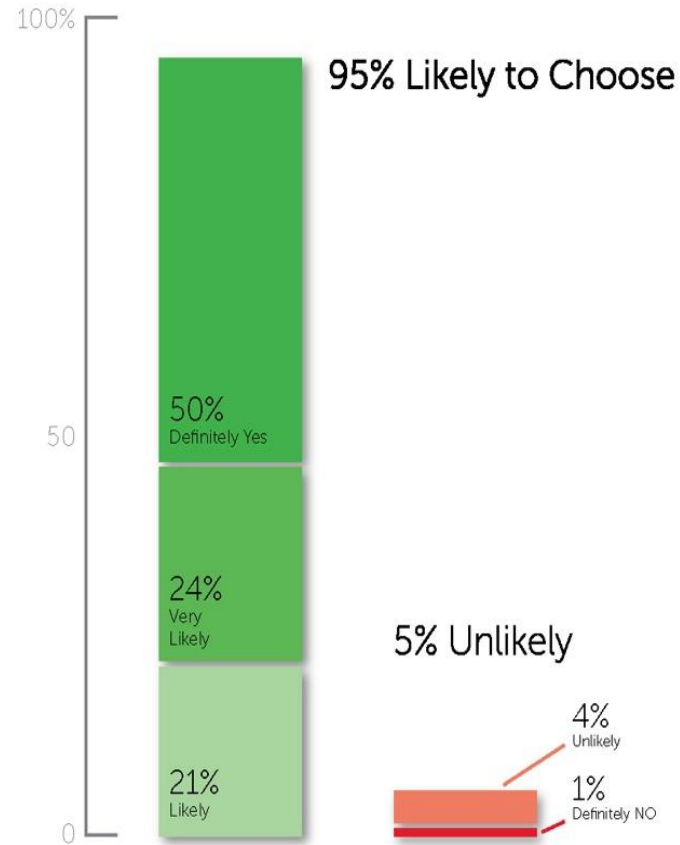
## 699 Needle-free injections – Nov. 2014



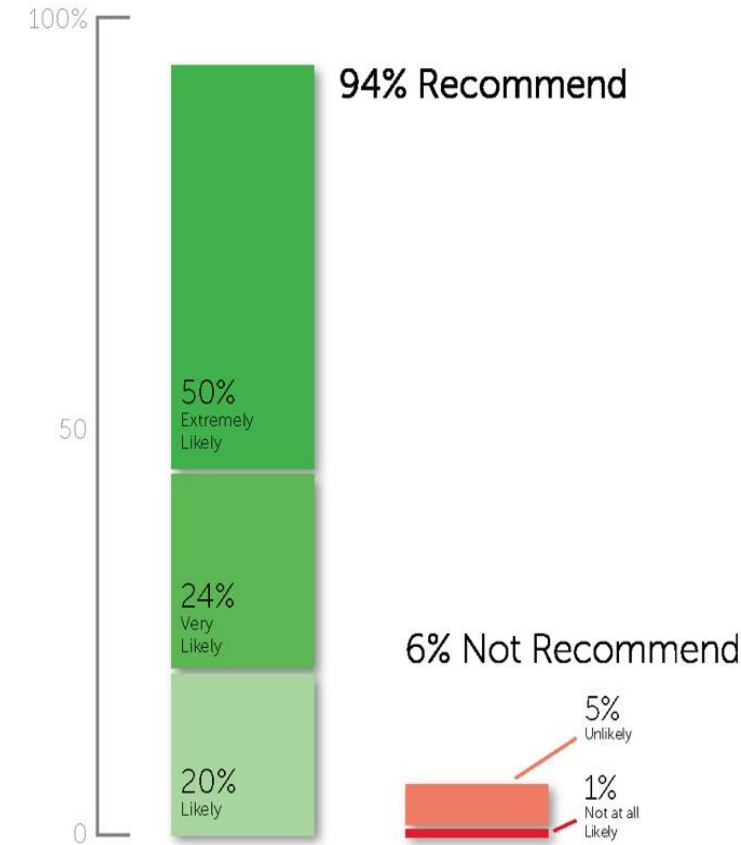
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How likely are you to recommend a Needle-Free Flu Shot to family and friends?

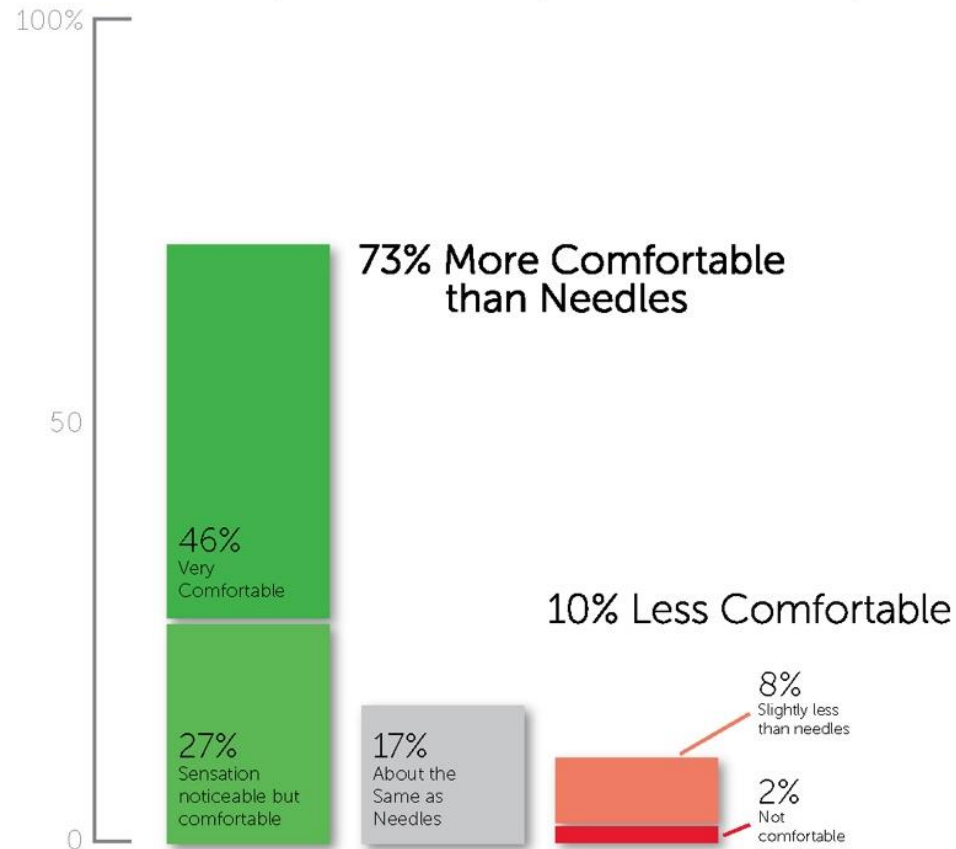


New Jersey Public Health, November, 2014

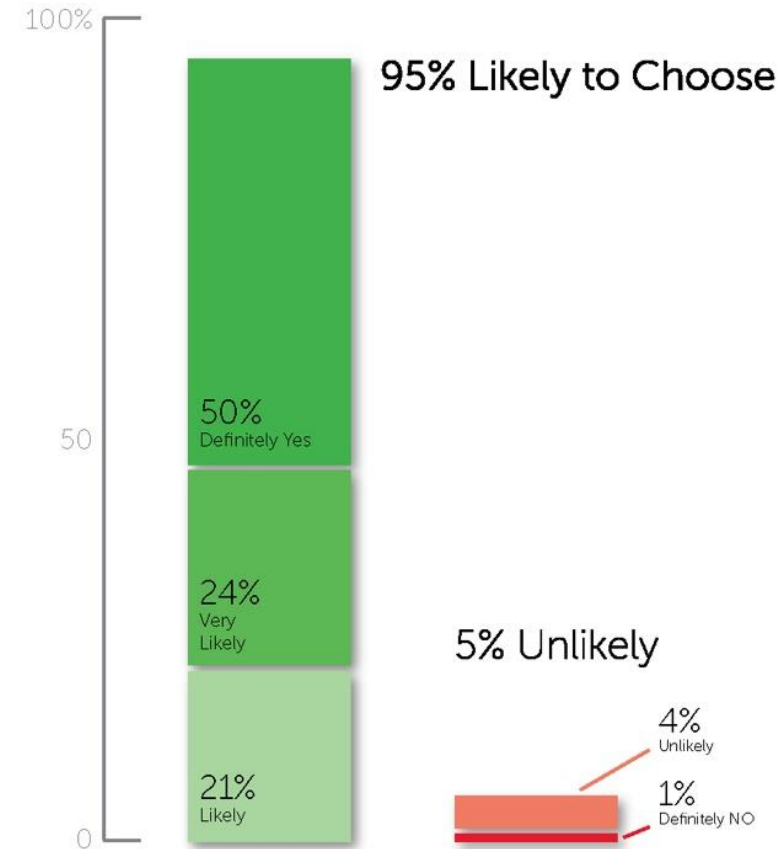
## 699 Needle-free injections – Nov. 2014



Considering all factors, compare how comfortable today's Needle-Free Injection was versus your previous needle injections.



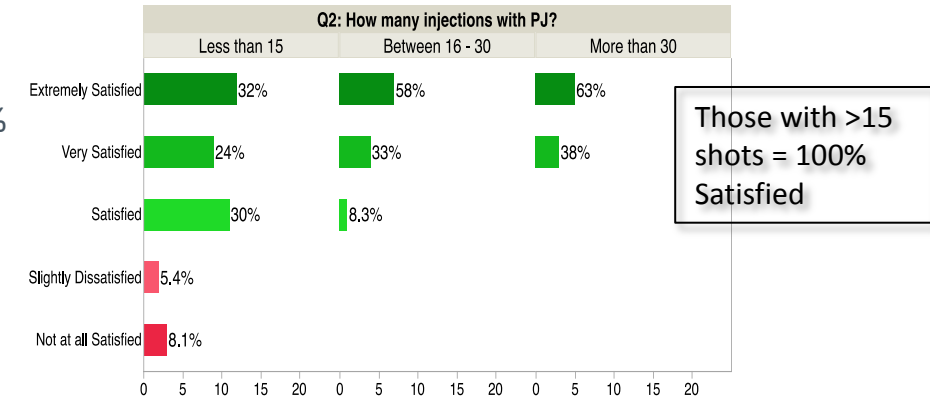
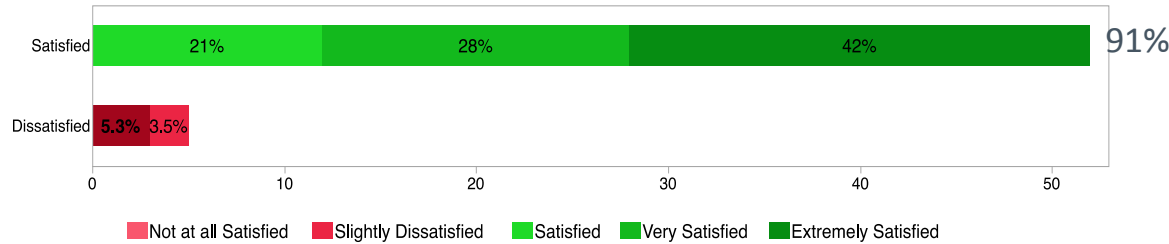
For next year's flu vaccination, will you choose to receive your flu shot with a Needle-Free Injection?



# User Experience Data - Healthcare Providers

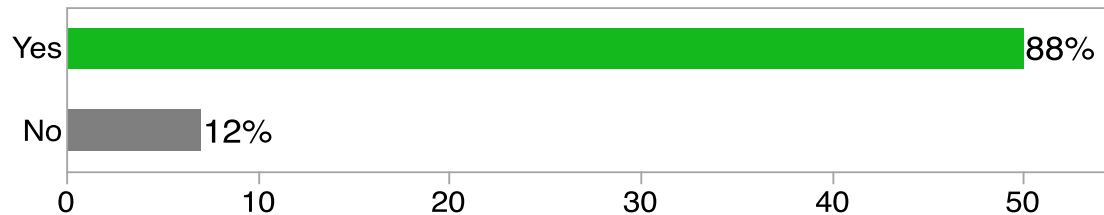
How satisfied were you with the Ease of Use?

91%  
Satisfied



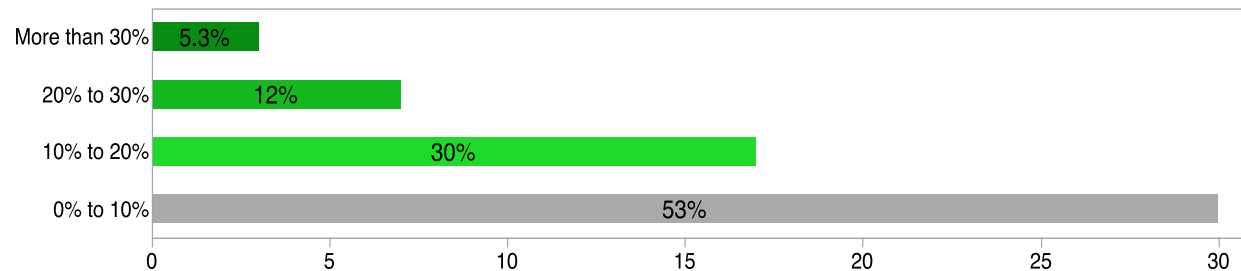
For next year's flu vaccinations, would you like the option of Needle-Free Shots at your facility?

88% Want  
Needle-Free



How much could your flu vaccinations increase next year by offering the option of a Needle-Free Flu Shot?

~50% believe  
immunization  
rates could  
increase >10%



# PharmaJet®

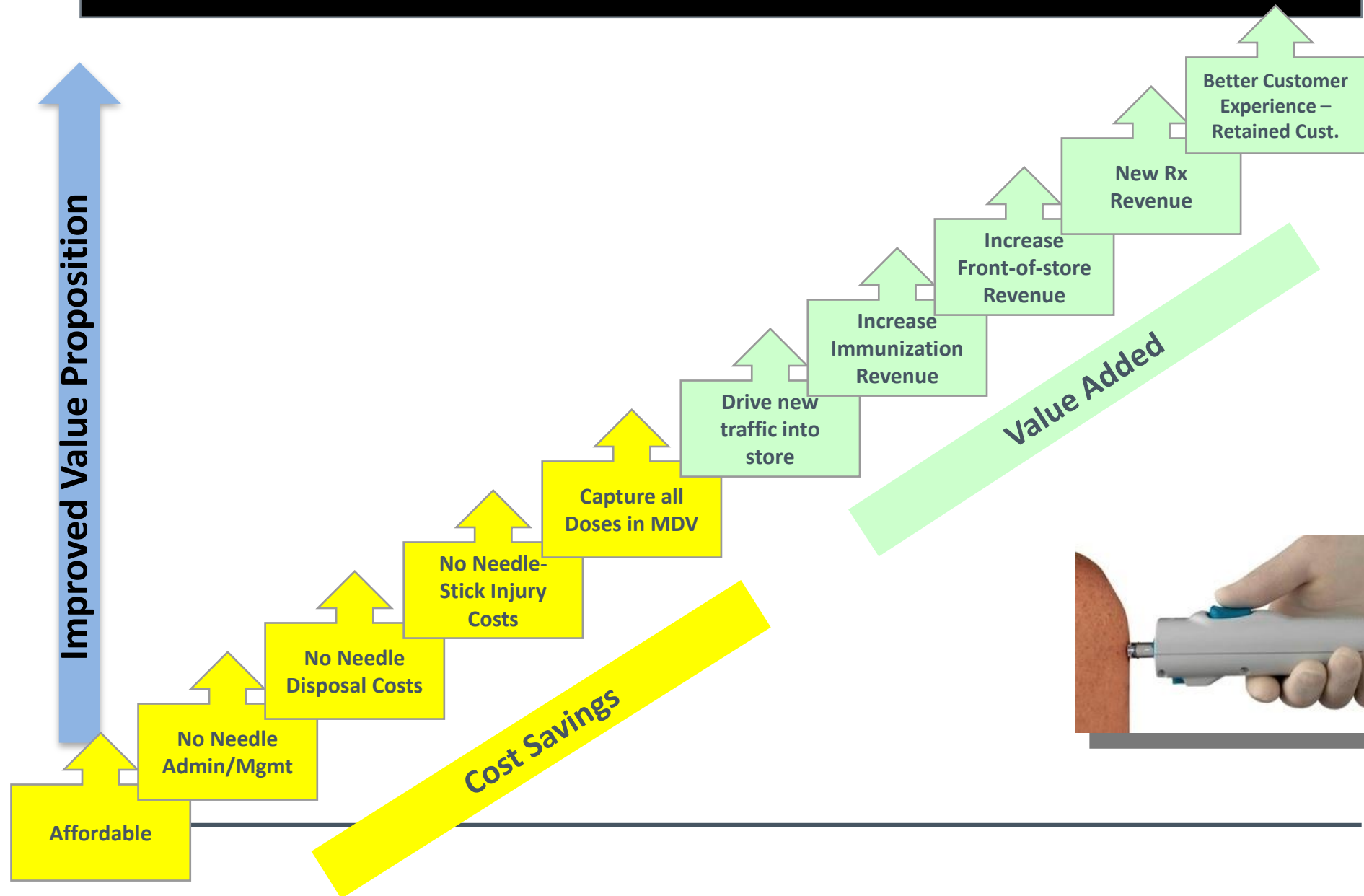
*Needle-Free Injection™*



Demonstrated Benefits



# Cost/Benefit Analysis



# Summary

## PharmaJet Needle-free Flu Shots

### 1. Product addresses market need

- › Problem = needles; Solution = Needle-free

### 2. Optimized Features and Benefits

- › *Stratis* design launched and field validated

### 3. Regulatory Clarity

- › FDA 510k clearance; And, specific labeling on **bioCSL Afluria** flu vaccine

### 4. Positive Clinical Results – safety and immunogenicity data

- › Published in August 2014 issue of The LANCET

### 5. Overwhelmingly positive user experience data – 2014 flu season

- › Patients and Healthcare Providers desire the *Stratis* Injector

### 6. Value added for User

- › Optimized product offering for best customer experience
- › Financial benefits flow through (no sharps, compliance, dose savings, cost savings)



# Overall Value of Needle-Free Injections

**PharmaJet provides a safe, effective, needle-free option for retail pharmacies, public health, and large hospital system users**

- 1. Expands customer choices** - providing patients with the most accessible care
  - Expands offering of vaccine and delivery options
- 2. Inspires patients to seek out immunization** - with differentiation of offering vs. needles
  - Creates excitement with a distinctive and innovative offering – word of mouth may contribute to more people being vaccinated
  - Addresses those that avoid immunization due to needles, but understand the importance or need for influenza immunization (first responders/public task employees, healthcare workers, hospital administrative and technical staff, and their family members)
- 3. New customers equate to measurable incremental sales**
  - Fosters conversations between pharmacy staff interaction and customers – new customers and increased purchase of other products
- 4. Safer Work Environment for Pharmacy Employees and Community**
  - Herd immunity (greater immunization range) has proven positive economic impact
  - Reduces needle-stick and pass along disease, testing, and disposal costs related to mass or high-volume immunization settings
- 5. Unique Positioning/Marketing/Advertising Opportunities**
  - Potential to offer unique solutions to today's healthcare challenges
  - Positions provider as an innovator offering new and safe alternative to needles

# Economic Value-Added for Pharmacies

- **Drive New Traffic into Stores**
  - Innovative Offering Attracts New Customers from Competition
- **Increased Immunization Revenue \$**
  - Vaccination Services Increased; Matches Pharmacy Corporate Focus
- **Increased Front-of-Store Revenue \$**
  - Larger Spend per Customer Store Visit
- **New Rx Script Customers**
  - New Customers that become long-term customers for prescriptions
- **Better Customer Experience**
  - Retained Customer
  - Pharmacy Staff-to-Customer Interaction yields 59% rate of purchasing a non-Rx products



# Educational Support

## ➤ Informational ([www.pharmajet.com](http://www.pharmajet.com))

- Videos
  - Pharmacist demonstration
  - Workflow comparison vs. needle & syringe

## ➤ Self-Training

- User Guide - Laminated workflow demonstration guide
- Educational Video - System components & workflow
- Webinar - Pre-recorded video with assessment tollgates
- Frequently Asked Questions
- Starter Kit (shipped with each hardware set)
  - Self-guided review of IFU and User Guide
  - Login registration as new user on website
  - Self-guided tour through Educational Roadmap

## ➤ PharmaJet conducted training (On demand)

- WebEx – individual and/or group hands on with Q&A
- On-Site Training
  - Train the Trainer
  - Initial implementation at stores/sites





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