What's in this Press Kit?

Thank you for your interest in SafeUseNow℠. This digital Press Kit includes several documents that introduce you to SafeUseNow and the company that developed this novel solution, Principled Strategies.

Included in this Press Kit are:

- SafeUseNow Executive Summary
- SafeUseNow Overview
- SafeUseNow Brochure
- Prescription Drug Abuse Fact Sheet
- Introduction to SafeUseNow PowerPoint
- SafeUseNow Press Releases
- Principled Strategies Overview
- Principled Strategies Brochure
- Principled Strategies Executive Biographies

Digital Press Kit

A digital version of this Press Kit can be found online at the SafeUseNow website. Or just scan the QR code below. The digital version of this Press Kit includes two SafeUseNow videos.

For more information, please contact:

Patrick J. Burns
President/CEO
Principled Strategies, Inc.
179 Calle Magdalena, Suite 200
Encinitas, CA 92024
760-230-6323
patrick.burns@safeusenow.com
www.safeusenow.com

About SafeUseNow

SafeUseNow is a novel, prescriber-centric solution and risk identification and intervention program to combat the spread of prescription drug abuse. Using multiple sources of data, advanced analytics, and a patent pending risk identification model our solution enables managed care organizations to identify those whose prescribing behaviors may contribute to prescription drug abuse.

The program was developed by Principled Strategies, a health care consultancy with expertise in predictive analytics, optimization and risk analysis.

About Principled Strategies

Principled Strategies leverages the power of predictive analytics, optimization, and risk analysis to create innovative, customized solutions that significantly improve our clients' performance.

Principled Strategies specializes in key aspects to optimizing healthcare, including strategy, advanced analytics, and economics.

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Rev. 9-2014

Executive Summary

Business Concept

SafeUseNow℠ is an integrated, actionable solution for systematically and efficiently combating prescription drug abuse risk using a behavioral risk model that evaluates prescriber, patient, and pharmacy data. Developed by Principled Strategies' experts in healthcare analytics, predictive modeling, and risk analysis, this healthcare technology solution has earned multiple Honors and National Stage Events in 2014:

- One of seven Knight News Challenge: Health winners
- Invited App Demo Presenter at Health Datapalooza 2014 (Washington, DC)
- Inducted into The Hive, a collective of the Top 60 Healthcare IT Products, at TEDMED 2014 (San Francisco, CA) on September 10-12.
- Invited App Demo presenter at Health 2.0

Clients
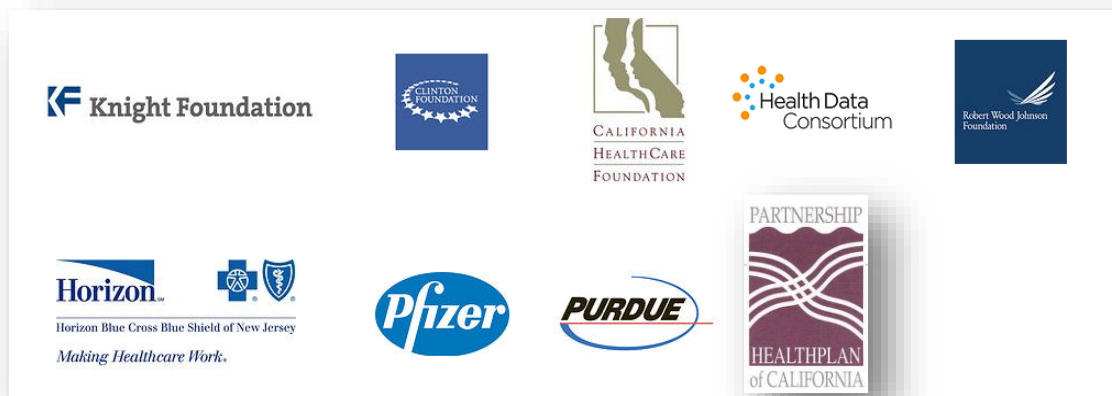
Clinical Validation

We recently completed a 3-year pilot program with Horizon Blue Cross Blue Shield of NJ. In April 2014 Horizon and Principled Strategies co-presented preliminary pharmacy cost reduction outcomes at the 2014 Academy of Managed Care Pharmacy (AMCP) annual exposition in Tampa, FL. We reported a $3.1M pharmacy cost reduction for a six-month intervention program which reached the 1,200 (0.8%) riskiest prescribers in this managed care organization's provider community. An assessment of associated medical cost reduction is currently underway and will be available for public distribution in early October 2014. Medical cost reduction is expected to be in the range of $3M-$6M.

SafeUseNow Product Line

The PSI Score™ behavioral risk model powers the SafeUseNow solution. The PSI Score model is an adaptation of a prescriber risk model that Principled Strategies developed in 2009 using national-level prescription transaction and longitudinal patient claims data.

To date, Principled Strategies has earned >$1M in revenue from the SafeUseNow pilot program and its early adopter clients.

Multiple healthcare stakeholder communities have expressed interest in Principled Strategies' national prescriber risk model research, and given the success of its managed care-oriented cousin, the PSI Score model, Principled Strategies seeks to enter into a business relationship with a national healthcare data provider in order to launch its second product: the National Risk model.
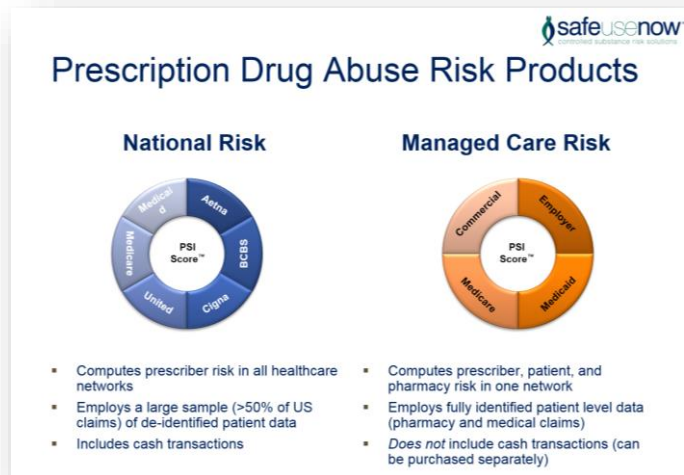
Total Addressable/Served Available/Target Market (YEAR 1)

Product	TAM[1]	SAM[2]	TM[3]
Managed Care Risk Model	$135.0M	$33.8M	$3.4M

[1] 300M health plan members in US * 15% controlled substance drug utilization * $0.25 per-member per-month * 12 months.
[2] Assume 25% share of total addressable market.
[3] Assume 10% share of served available market.

Product	TAM[1]	SAM[2]	TM[3]
National Risk Model	$75M	$18.8M	$1.8M

[1] 500 companies of size with requisite risk management need * $150K per year (average sale size)
[2] Assume 25% share of total addressable market.
[3] Assume 10% share of served available market.

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About SafeUseNow

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SafeUseNow Overview

SafeUseNow℠ is a risk identification and intervention program developed by Principled Strategies, a health care consultancy with expertise in predictive analytics, optimization, and risk analysis.

The SafeUseNow advantage is 17 predictive risk factors discovered in a multiyear study of physician prescribing, pharmacy dispensing, and patient utilization of controlled substances. SafeUseNow is an actionable solution for systematically and efficiently combating the misuse, abuse, addiction and diversion of controlled substances.

SafeUseNow is specifically designed to provide immediate benefit to:

- Private Health Insurance Plans
- Public Health Insurance Plans
- Pharmacy Benefit Managers
- Self-insured Employers

SafeUseNow is a novel, prescriber-centric solution to combating prescription drug abuse. Using multiple sources of data, advanced analytics, and a patent pending risk identification model our solution enables managed care organizations to identify those whose prescribing behaviors may contribute to prescription drug abuse.

Because prescribers are the primary source of prescription drugs, efforts to reduce prescription drug abuse must begin with them, and must identify, engage, and monitor them.

IDENTIFY those whose prescribing behaviors may contribute to prescription drug misuse, abuse, addiction, and diversion and stratify them by risk severity using the PSI Score™ model.

- PSI Score is a composite measure of risk
- Calculated using a weighted combination of multiple risk factors
- Scores computed monthly using automated data feeds
- Identify demographic and geographic trends
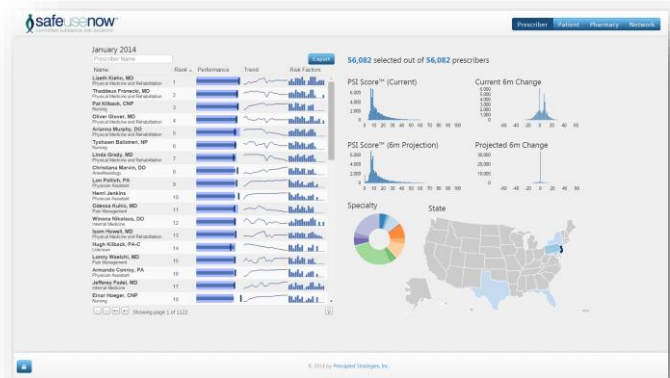- Analyze changes in prescribing behavior over time

ENGAGE prescribers in an educational program designed to improve appropriate prescription drug prescribing.

- Designed to effectively engage and educate each prescriber
- Presents risk-class appropriate strategies to minimize abuse
- Promotes appropriate prescribing and patient safety
- Uses a Social Learning theory framework
- Customized 1:1 interaction with each prescriber
- Optimizes responsiveness and behavior change

MONITOR prescribing patterns to detect changes in behavior and measure the effectiveness of the intervention program.

- Measures prescriber behavior change over time
- Feedback loop to improve intervention services effectiveness
- Identifies prescribers who refuse to engage in the program
- Identifies prescribers who are unresponsive to the program
- Triages resistant prescribers to other risk management functions

About SafeUseNow

SafeUseNow is a novel, prescriber-centric solution and risk identification and intervention program to combat the spread of prescription drug abuse. Using multiple sources of data, advanced analytics, and a patent pending risk identification model our solution enables managed care organizations to identify those whose prescribing behaviors may contribute to prescription drug abuse.

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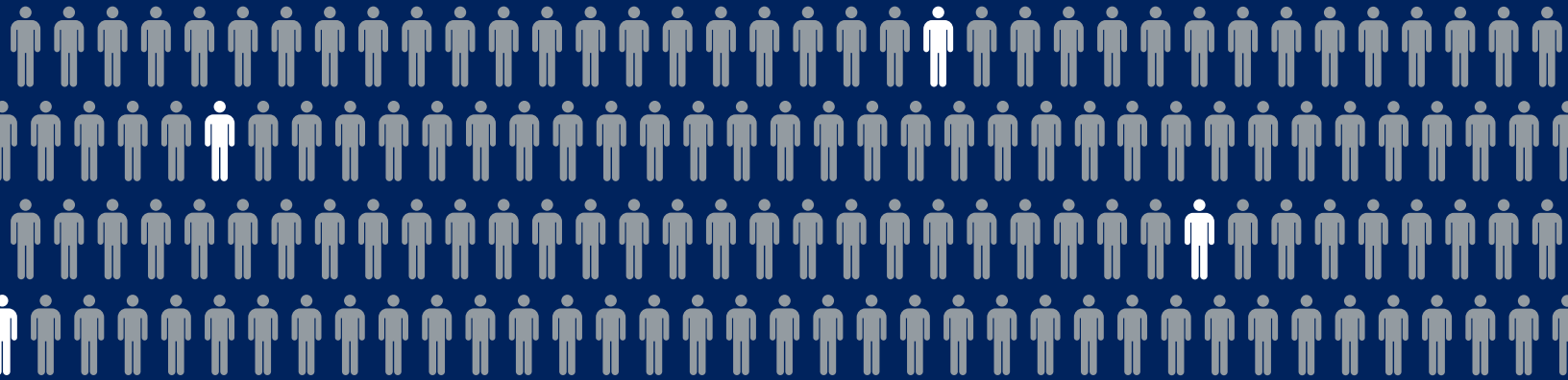
safeusenow ℠
controlled substance risk solutions

predictive solutions
misuse · abuse · addiction · diversion

prescriber · patient · pharmacy

identification · intervention

www.safeusenow.com

powered by a patent pending risk model

The Problem

Since the 1990s there has been a dramatic increase in prescription drug abuse in the U.S. Non-medical use of prescription drugs is now the nation's second leading cause of accidental death [1]. A study of commercially insured beneficiaries in the U.S. found that mean per-capita annual direct health care costs from 1998 to 2002 were nearly $16,000 for abusers of prescription and nonprescription opioids compared with approximately $1,800 for non-abusers.

This epidemic has led to increased regulatory scrutiny at both the federal and state level. Today, forty states have operational prescription drug monitoring programs (PDMP or PMP). Of the remaining 10 states eight are in the process of operationalizing a PMP while two have PMP legislation pending. PMPs, however, employ a *patient-centric* model for combatting the problem, with a primary goal being to identify and treat persons addicted to prescription drugs [2]. Most have been unsuccessful [3]. Only three focus on prescribers and proactively provide education about prescription drug abuse.

Our Solution

SafeUseNow℠ is a novel, *prescriber-centric* solution to combating prescription drug abuse. Using multiple sources of data, advanced analytics, and a *patent pending risk identification model* our solution enables managed care organizations to identify network providers whose prescribing behaviors may contribute to prescription drug abuse.

Because prescribers are the primary source of prescription drugs, efforts to reduce prescription drug abuse must begin with them, and must accomplish three objectives:

1. ***Identify*** *those whose prescribing behaviors may contribute to prescription drug abuse, and stratify them by risk severity;*

2. ***Engage*** *prescribers in an educational program designed to improve appropriate prescription drug prescribing; and*

3. ***Monitor*** *prescribing patterns to detect changes in behavior and measure the effectiveness of the intervention program.*


Identify

The **PSI Score™** model uses prescriber-level and anonymous patient-level data to estimate *prescription drug abuse risk* for individual prescribers. The model was originally developed to estimate OxyContin® abuse risk for 500,000 prescribers in the U.S., and is highly accurate having correctly classified 83% of known problem prescribers in a multi-year validation trial [4].

The **PSI Score™** is a holistic measure of individual prescriber risk within a managed care network. This multi-dimensional measure assimilates three categories of risk:

1. Individual prescriber behavior;
2. Behavior of patient(s) being treated by that prescriber; and
3. Behavior of other prescribers treating the same patients.

The **PSI Score™** is also a hierarchical risk measure. It is calculated using a weighted combination of multiple *risk factors*. Scores for an entire provider network are computed monthly using automated data updates. By aggregating scores for sub-populations of prescribers, demographic and geographic trends can be identified. Individual and aggregate trend data can be used to analyze changes in prescribing behavior over time.


Ranking and stratifying prescribers by **PSI Score™** and its component risk factors enables the delivery of intervention services tailored to each prescriber's risk factors and risk severity. Moreover, the program flags and prioritizes prescribers whose **PSI Score™** indicates a rapid trend toward increased risk, enabling managed care organizations to match intervention services to the inherent risk in their provider network.
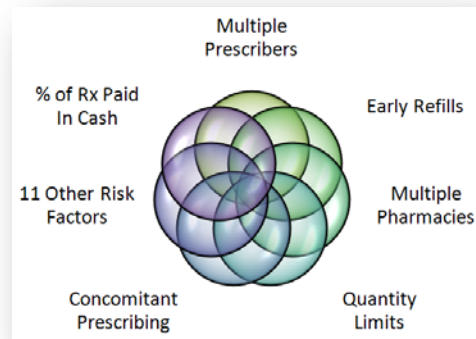
Engage

Our prescriber intervention services are designed to effectively engage and educate prescribers about risk-class appropriate strategies to minimize prescription drug abuse and promote best practices for appropriate prescribing and patient safety.

Using Social Learning theory [5,6] as a framework for customizing interactions with prescribers based on their level of motivation versus resistance, our intervention program optimizes responsiveness and behavior change among the largest possible number of prescribers. The program uses multiple communication channels (e.g., letter, email, telephone coaching, and academic detail) to allow prescribers to choose their preferred method to establish ongoing 2-way communication with the program. Soliciting continuous feedback from prescribers, the program tailors messages to address prescriber's risk behaviors as well as their motivation versus resistance to engage in the intervention and adopt recommended best practices. Live coaching from licensed pharmacists is used to present individualized risk factors. Learning modules related to each risk factor present guidelines regarding best practices, such as showing prescribers how to conduct assessments, create patient

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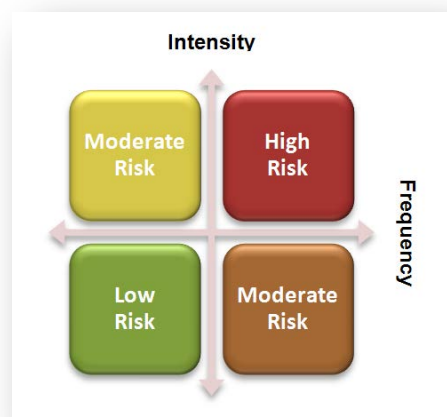
agreements, and manage difficult patient interactions to reduce risk of addiction and diversion.

The frequency and intensity of the intervention services is tailored to risk severity so that one-on-one encounters are reserved for the high risk population while low-cost encounter channels can be deployed to the low risk population to save resources. Experimental design methodology can be employed to pursue maximum impact across the MCO network.

When the **PSI Score™** model identifies a prescriber as potentially engaging in multiple risk behaviors, a prioritization algorithm determines the appropriate sequence to bring each behavior to the prescriber's attention to maximize engagement and rapidly reduce any risk the prescriber's behavior may pose to patients.
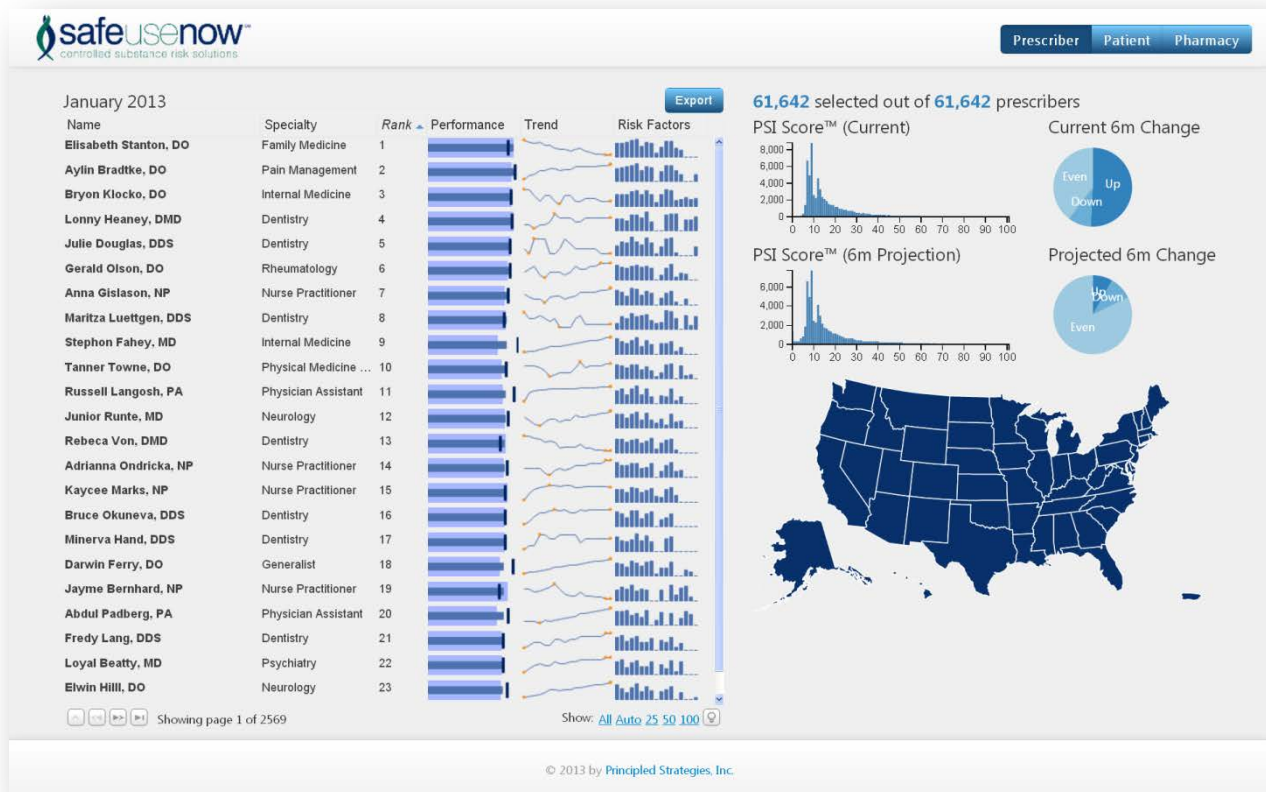
To promote engagement and adoption, the program offers prescriber services through clinical pharmacists and a secure Web portal. One service, for example, enables prescribers to review a list of patients who were recently prescribed a controlled drug or a relevant concomitant drug by another prescriber in the past 30 days, or who received prescriptions from multiple pharmacies, and to lock those patients into receiving future prescriptions from only one prescriber and one pharmacy.

Monitor

The program measures behavior change over time so that the effectiveness of the intervention services can be improved. It also identifies prescribers who are unresponsive to the program or refuse to engage in the program, so that they can then be triaged to other risk management functions within the MCO.

To Learn More

For more information about SafeUseNow℠ please contact:

> **Patrick J. Burns**
> President
> (760) 230-6320 x323
> patrick.burns@safeusenow.com

> **Lawrence Feinstein, PhD**
> Vice President, Clinical Programs
> (760) 230-6320 x329
> lawrence.feinstein@safeusenow.com

About SafeUseNow℠

Principled Strategies, creator of the SafeUseNow℠ program, leverages the power of predictive analytics, optimization, and risk analysis to create innovative, customized solutions designed to mitigate risk. Principled Strategies specializes in strategy, advanced analytics, and economics, and is based north of San Diego in the seaside community of Encinitas, CA.

References

[1] *Drug deaths now outnumber traffic fatalities in U.S., data show*. September 17, 2011. Lisa Girion, Scott Glover and Doug Smith, Los Angeles Times.

[2] *State Prescription Drug Monitoring Programs*. Questions & Answers 2011 [cited 2011 11/01/2011]; Available from: http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm#1

[3] Manchikanti, L., *Prescription drug abuse: what is being done to address this new drug epidemic? Testimony before the Subcommittee on Criminal Justice, Drug Policy and Human Resources.* Pain Physician, 2006. **9**(4): p. 287-321.

[4] Poster presented at the 2011 Annual Meeting of the College on Problems of Drug Dependence (CPDD).

[5] Bandura, A. (1977). *Social learning theory*. Englewood Cliffs, NJ: Prentice-Hall

[6] Meichenbaum, D. (1977). *Cognitive-behavior modification: An integrative approach*. New York:Plenum.

Prescription Drug Abuse: A National Epidemic

Since the 1990s, prescription drug abuse has skyrocketed in the United States. Prescription drug overdose deaths recently surpassed motor vehicle accidents as the #1 cause of accidental death in the U.S. This problem affects friends, loved ones, schoolmates, colleagues and employees. More than ever, there is a critical need for an effective identification and intervention solution. That's why SafeUseNow℠ was created.

The source of the problem
Would it surprise you to learn that less than 5 percent of abused pharmaceutical drugs come from street dealers or strangers? In fact, prescription drugs most often come directly from the medicine cabinets of friends and family. And where do those prescription drugs come from?

They come from the family physician. They come from your dentist. They come from the specialist you see for an outpatient surgery. They come from your healthcare practitioner. According to our analysis of SAMHSA data, between 2004-2009 prescription drug abuse treatment costs have grown 15.6% annually. It has been reported, too, that our U.S. population consumes almost 80% of opioids prescribed in the world.

SafeUseNow: Combatting the problem
SafeUseNow is an actionable solution for systematically and efficiently combating the misuse, abuse, addiction and diversion of controlled substances. It evolved from a research study designed to predict physicians most likely to lose their medical license due to unsafe prescribing of opioid prescription drugs, like OxyContin®. In response, we developed a risk prediction algorithm using dozens of metrics of individual prescribing behavior for more than 500,000 U.S. opioid prescribers in the period 2007-2008.

Our product is not only inventive and innovative, it is disruptive because we don't ignore the elephant in the room. SafeUseNow may be the only explicitly *prescriber-centric solution* to mitigating prescription drug abuse risk.

SafeUseNow and Horizon BCBS of NJ Outcomes Study

Horizon Blue Cross Blue Shield of New Jersey recently completed a 3-year SafeUseNow pilot program. The pilot program included a 6-month risk education program for 1,200 high risk prescribers treating 250K Horizon members with one or more controlled substance drugs. Horizon and SafeUseNow co-presented an outcomes study of the pilot program at the Academy of Managed Care Pharmacy's (AMCP) 26th Annual Meeting & Exposition in Tampa, FL in April 2014. The study achieved eight of nine clinical endpoints, resulting in $3.1M in annualized pharmacy cost savings. A follow-on medical cost impact study has estimated another $5M-$7M in savings, bringing total program savings to between $8.1-$10.1M.

10 Shocking Prescription Drug Abuse Statistics

1. 75.2% of pharmaceutical deaths involved opioids, either alone or in combination with other drugs.
   Source: CDC, 2010.

2. Data released by the National Center for Health Statistics show drug overdose deaths increased for the 11th consecutive year in 2010.
   Source: NCHS, 2011.

3. The number of opioid analgesic prescriptions filled at pharmacies has increased from 175 million in 2000 to 254 million in 2009.
   Source: CDC, 2010.

4. In 2008, over 14,800 died from abuse of prescription painkillers.
   Source: CDC MMWR, 2011.

5. For every one prescription painkiller death, there are:
   - 10 treatment admissions for abuse.
   - 32 emergency room visits for misuse or abuse.
   - 130 people who abuse or are dependent.
   - 825 non-medical users.
   Source: CDC MMWR, 2011.

6. The average annual per patient health care costs are $15,884 to $18,388 among abusers, and $1,830 to $2,210 among non-abusers.
   Source: JMCP, 2005.

7. The National Survey on Drug Use reports that 11.4% of young people ages 12 to 25 used prescription drugs non-medically within the past year.
   Source: NSDU, 2010.

8. When asked how prescription narcotics were obtained for non-medical use, 70% of 12th graders said they were given to them by a friend or relative.
   Source: NIH/NIDA (MTF), 2011.

9. Among adolescents, prescription and over-the-counter medications account for most of the commonly abused illicit drugs by high school seniors.
   Source: NIH/NIDA, 2011.

10. Nearly 1 in 12 high school seniors reported non-medical use of Vicodin; 1 in 20 reported abuse of OxyContin.
    Source: NIH/NIDA, 2011.

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Introduction to SafeUseNow℠

September 2014

Agenda

- About SafeUseNow℠
- Pilot Program Overview
- Business Case

About SafeUseNow℠

Section 1

About Us

- Integrated, actionable solutions for systematically and efficiently combating prescription drug abuse risk
  - Prescriber ↔ Patient ↔ Pharmacy
- Developed by experts in healthcare analytics, optimization, and risk analysis
- 2014 Honors & National Stage Events
  - One of seven **Knight News Challenge: Health** winners
  - Invited App Demo Presenter @ **Health Datapalooza 2014**
  - Inducted into The Hive at **TedMed 2014**
  - Selected as a main stage app demo presenter at **Health 2.0**

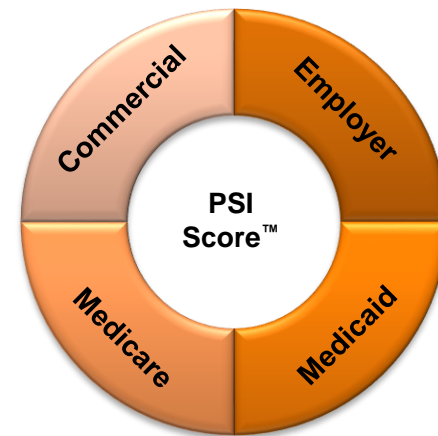# Clients & Research Partners

Product Offerings

- Current: Prescription Drug Abuse Risk
  - Managed Care Model
  - National Model

- Future: Cost of Care Reduction
  - Disease-specific models by annual cost of care (Source: WebMD 2013)
    » Cardiovascular $107.2B
    » Mental Disorder $73B
    » COPD & Asthma $63.8B
    » Join Disorders $62.4B
    » Diabetes $51.3B
    » High Blood Pressure $42.9B

Prescription Drug Abuse Risk Products

National Risk

A ring diagram labeled with segments: Medicaid, Aetna, Medicare, BCBS, United, Cigna, with **PSI Score™** in the center.

- Computes prescriber risk in all healthcare networks
- Employs a large sample (>50% of US claims) of de-identified patient data
- Includes cash transactions

Managed Care Risk

A ring diagram labeled with segments: Commercial, Employer, Medicare, Medicaid, with **PSI Score™** in the center.

- Computes prescriber, patient, and pharmacy risk in one network
- Employs fully identified patient level data (pharmacy and medical claims)
- *Does not* include cash transactions (can be purchased separately)

Pilot Program
with Horizon® Blue Cross Blue Shield of New Jersey

Section 2

Outcomes

- **Key Statistics**
  - Pharmacy
    - » 1.5M claims, 0.3M members, and 0.1M prescribers
  - Medical
    - » Data collection underway
    - » Results available in Oct 2014
- **Methodology**
  - Treatment-Control Comparison using Population Health Alliance (formerly Care Continuum Alliance) Guidelines
  - Outcomes co-presented with Horizon at the AMCP 26th Annual Meeting & Expo in Tampa, FL (Apr 2014)
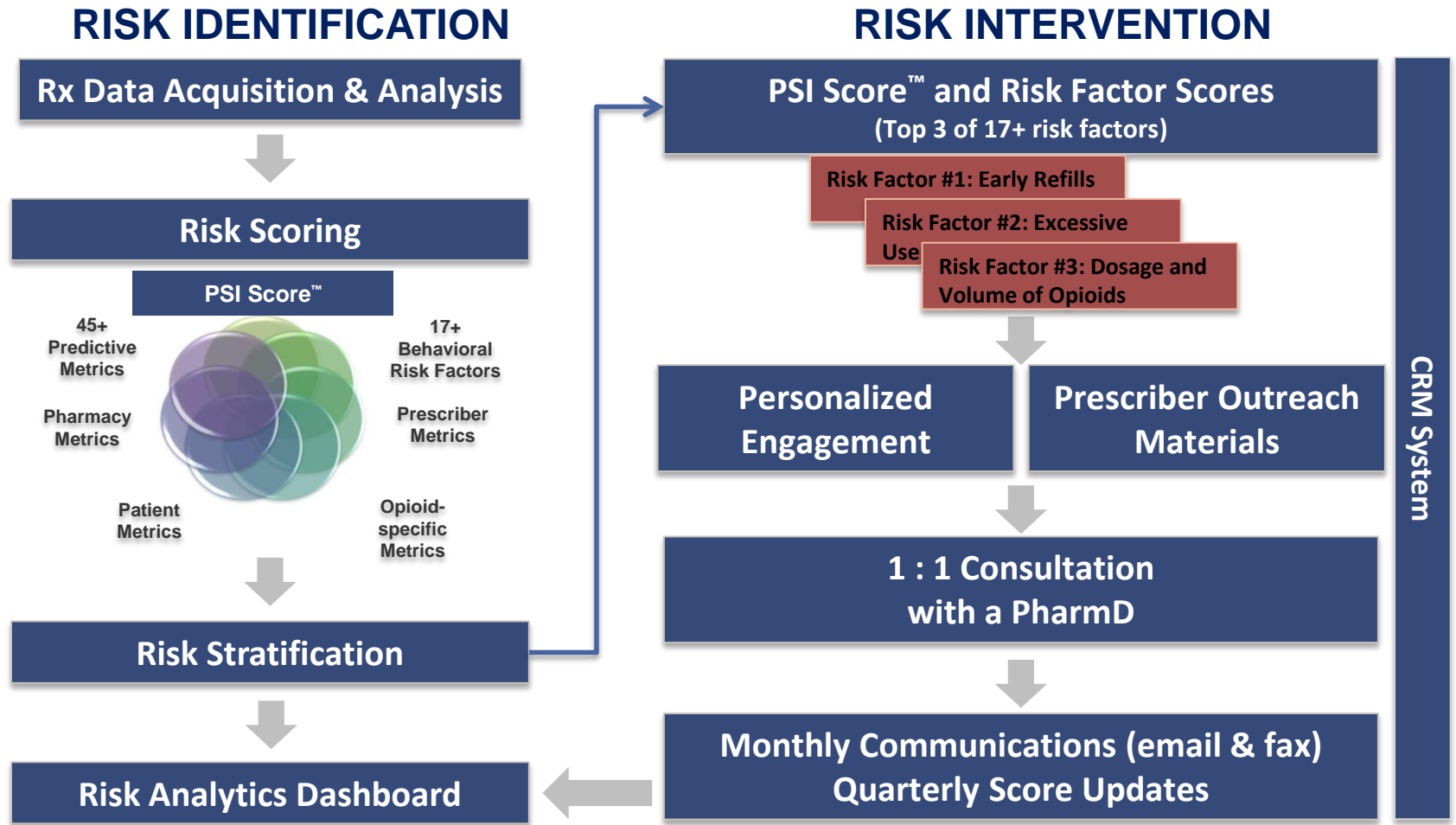
9-Month Post-Intervention Outcomes

Endpoint	Model Significance	P	Savings
Opioid Rx Claims Cost	Yes	= 0.041	$2,596,189
Non-opioid Rx Claims Cost	Yes	= 0.045	$461,731
Total (Annualized)			**$3,057,920**
Benefit-to-Cost			**4.4 : 1**

Notes
- Achieved model significance in 4 of 4 risk endpoints: PSI Score™, Multiple Prescribers, Multiple Pharmacies, and Concomitance.
- Achieved model significance in 1 of 2 utilization endpoints: Morphine Equivalent Dose (mg), NOT Opioid Prescription Claims.
- Achieved model significance in 2 of 2 cost endpoints: Opioid Rx Claims and Non-opioid Rx Claims.
- Annualized savings shown based on an assessment of 9-month post-intervention outcomes.

- **Program returned 4.4x the investment in *pharmacy cost savings* alone**
- **Medical cost savings estimated to be $5M - $7M; results in Oct 2014**

Key Phases

RISK IDENTIFICATION

Rx Data Acquisition & Analysis

↓

Risk Scoring

PSI Score™

45+ Predictive Metrics

17+ Behavioral Risk Factors

Pharmacy Metrics

Prescriber Metrics

Patient Metrics

Opioid-specific Metrics

↓

Risk Stratification

↓

Risk Analytics Dashboard

RISK INTERVENTION

PSI Score™ and Risk Factor Scores
(Top 3 of 17+ risk factors)

Risk Factor #1: Early Refills

Risk Factor #2: Excessive Use

Risk Factor #3: Dosage and Volume of Opioids

↓

Personalized Engagement | **Prescriber Outreach Materials**

↓

1 : 1 Consultation with a PharmD

↓

Monthly Communications (email & fax) Quarterly Score Updates

CRM System

Risk Analytics Dashboard Demo

Names are fictitious
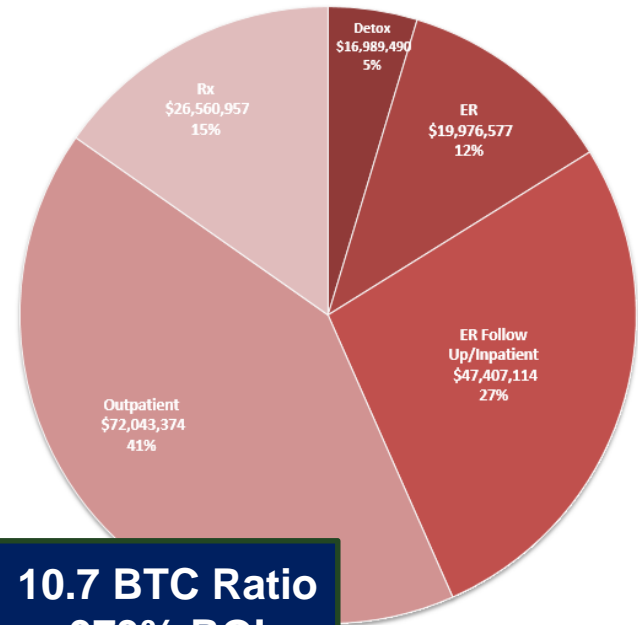
Business Case

Section 3

Program Impact Scenario: 3.2M Members

$20.3M total savings (3 year)

$174.1 total cost burden (3 year)

SafeUseNow℠ Program
Abuse, Misuse, Addition & Diversion (AMA&D) Economic Impact Model

Average Annual Growth Rate:	15.6%		*For period 2004-2009*
	15.6%		*Enter expected average annual growth rate for 2014-2016*
Insured Population:	1,000,000		*Enter # members in 2014*
Age:	(All)		*Select insured population age range*
Drug Group:	(All)		*Select drugs of interest*

Costs	2014	2015	2016	3-Year Total
SafeUseNow℠ Program Cost:	$ 630,000	$ 630,000	$ 630,000	$ 1,890,000
Estimated AMA&D Cost Exposure:	$ 48,659,570	$ 57,504,848	$ 67,958,010	$ 174,122,429

Estimated Savings	2014	2015	2016	3-Year Total
Projected Impact:	10.0%	6.6%	3.3%	6.3%
Projected Gross Annual Savings:	$ 4,865,957	$ 3,795,320	$ 2,242,614	$ 10,903,891
Retained Savings Rate:	0%	80%	80%	
Retained Savings from Previous Year:	$ -	$ 3,892,766	$ 5,944,930	$ 9,837,696
Projected Net Annual Savings:	$ 4,865,957	$ 3,538,397	$ 2,046,432	$ 10,450,786
Total Savings:	$ 4,865,957	$ 7,431,163	$ 7,991,362	$ 20,288,482

	2014	2015	2016	
Benefit-to-Cost Ratio: Annual	7.7	11.8	12.7	10.7
Cumulative	7.7	9.8	10.7	
ROI: Annual	672%	1080%	1168%	973%
Cumulative	672%	876%	973%	

10.7 BTC Ratio 973% ROI

Pie chart:
- Detox $16,989,490 5%
- ER $19,976,577 12%
- ER Follow Up/Inpatient $47,407,114 27%
- Outpatient $72,043,374 41%
- Rx $26,560,957 15%

For further information

Patrick J. Burns

President/CEO

Principled Strategies, Inc.

179 Calle Magdalena, Suite 200

Encinitas, CA 92024

O: 760-230-6323

C: 858-699-1732

patrick.burns@safeusenow.com

www.safeusenow.com

Introduction to SafeUseNow℠

September 2014

SafeUseNow Wins 2014 Knight News Challenge: Health Award; Project to help reduce prescription drug abuse in the United States

SafeUseNow will use data to identify incidents of prescription drug abuse with $208,000 in funding, as a winner of the Knight News Challenge: Health. Winners were announced Tuesday at the Clinton Foundation 2014 Health Matters conference in La Quinta, California.

Encinitas, CA (PRWEB) January 17, 2014 -- SafeUseNow□ will use data to identify incidents of prescription drug abuse with $208,000 in funding, as a winner of the Knight News Challenge: Health.

The challenge, launched in August 2013 by the John S. and James L. Knight Foundation, sought ideas that harness the power of data and information for the health of communities. Winners were announced Tuesday at the Clinton Foundation 2014 Health Matters conference in La Quinta, California.

The winning SafeUseNow□ submission is titled, "A Solution for California's Local Community Health Plans to Reduce the Risk and Cost of Prescription Drug Abuse." Since the 1990s, prescription drug abuse has significantly increased in the United States. However, a lack of actionable information about prescription drug abuse risk, despite the increase of state monitoring programs, makes it difficult to combat the problem.

SafeUseNow□ aims to help reduce abuse by making prescribing safer and more effective. The program uses data to identify combinations of prescribers, patients and pharmacies who may be contributing to the problem. This information helps pharmacies, insurance companies and other health care stakeholders educate prescribers to more effectively and safely treat patients. It also allows them to monitor prescribing patterns for changes in trends and behavior. A successful pilot with one health plan provider achieved a significant reduction in key risk factors. With Knight Foundation funding, the team will scale the project for use by Medicaid plans in California and aims to spread around the country.

"We are thrilled with our selection as a Knight News Challenge winner," said Patrick J. Burns, President of Principled Strategies, the Encinitas, California-based developer of SafeUseNow□. "The prescription drug abuse rate in our Medicaid population is 10 times the rate in the privately insured population. This grant funds delivery of a powerful, validated prescription drug abuse solution to a progressive Medicaid health plan that is ready and eager to aggressively tackle this problem."

"SafeUseNow□ uses data to address a pervasive problem," said Michael Maness, Knight Foundation vice president of journalism and media innovation. "Prescription drug abuse is an issue that communities can engage around, revealing the impact that data can have on their lives."

About SafeUseNow□
SafeUseNow□ is a risk identification and intervention program developed by Principled Strategies, a health care consultancy with expertise in predictive analytics, optimization, and risk analysis. The SafeUseNow□ advantage is 17 predictive risk factors discovered in a multi-year study of physician prescribing, pharmacy dispensing, and patient utilization of controlled substances. SafeUseNow□ is an actionable solution for systematically and efficiently combating the misuse, abuse, addiction and diversion of controlled substances.

For more, visit www.safeusenow.com and follow #safeusenow on Twitter.

Twitter: @SafeUseNow, @PJBatSUN
Video: http://kng.ht/1991yzg

About the Knight Foundation
The John S. and James L. Knight Foundation promotes journalism excellence world-wide and invests in the vitality of communities in the Unites States where the Knight brothers once owned newspapers. Knight Foundation invests in ideas and projects that can lead to transformational change.

Contacts:
Patrick J. Burns, President, Principled Strategies, 760-230-6323, patrick.burns(at)safeusenow.com

Anusha Alikhan, Director of Communications, John S. and James L. Knight Foundation, 305-908-2677, media(at)knightfoundation.org

Contact Information
Patrick J. Burns
Principled Strategies, Inc.
http://www.safeusenow.com
+1 (760) 230-6323

Online Web 2.0 Version
You can read the online version of this press release here.

FOR IMMEDIATE RELEASE

Contact: Patrick J. Burns, President, Principled Strategies
Tel.: (760) 230-6323 | email: patrick.burns@safeusenow.com

Partnership HealthPlan of California signs program participation agreement with SafeUseNow

One of California's leading Medicaid plans adopts SafeUseNow to quickly identify and help stop prescription drug abuse

ENCINITAS, Calif. July 23, 2014 - <u>SafeUseNow</u>℠, a prescription drug abuse risk identification and intervention program developed by <u>Principled Strategies</u>, today announced a service agreement with <u>Partnership HealthPlan of California</u>. Utilizing SafeUseNow's patent-pending risk model, Partnership HealthPlan can quickly identify patients at risk of misusing and abusing controlled substance drugs, particularly prescription opioids, helping the Plan to reduce addiction among its members.

The agreement with Partnership HealthPlan was made possible through support from the <u>John A. and James L. Knight Foundation to SafeUseNow</u>, which offers a proven program to identify combinations of prescribers, patients and pharmacies at risk of contributing to the prescription drug abuse problem.

"We are thrilled to work with Partnership HealthPlan of California as the first Medicaid plan in the state to utilize SafeUseNow to identify, intervene and help reduce prescription drug abuse risk," said Patrick J. Burns, president of Principled Strategies. "With the assistance of the Knight Foundation grant, we can help the members of Partnership HealthPlan in 14 Northern California counties live healthier lives, and enable prescribing physicians contracted with the Plan to improve their prescribing practices to avoid abusive prescription drug use."

"Partnership HealthPlan is pleased to be selected to test the SafeUseNow product in a Medi-Cal (California's version of Medicaid) population," said Robert L. Moore, MD, MPH, chief medical officer of Partnership HealthPlan. "Having prescriber-specific risk scores and recommendations for safer prescribing is a key component to our plan-wide initiative to manage pain more safely."

Partnership HealthPlan of California is the latest in a growing number of leading national health insurance plans and pharmaceutical manufacturers to adopt SafeUseNow's prescription drug abuse risk identification and intervention services. SafeUseNow is helping reduce the growing problem of opioid drug abuse by making prescribing safer and more effective.

SafeUseNow delivers actionable information to help healthcare stakeholders educate prescribers to more effectively and safely treat their patients. SafeUseNow also allow customers to proactively monitor prescribing patterns for early detection of changes in prescribing trends and behavior.

Since the 1990s, prescription drug abuse has significantly increased in the United States, making the need for an effective identification and intervention solution critical. Until the development of SafeUseNow, a lack of actionable information about prescription drug abuse risk, despite the creation of state-sponsored prescription drug monitoring programs, made it difficult to combat the problem.

SafeUseNow was named a winner of the Knight News Challenge: Health in January 2014. The challenge, supported by the John S. and James L. Knight Foundation, sought ideas that harness the power of data and information for the health of communities. With Knight Foundation funding, SafeUseNow will scale its services for use by Medicaid plans in California as well as leading national health insurance carriers, Blue Cross Blue Shield plans and pharmaceutical manufacturers.

"SafeUseNow is applying data and information to help address a pervasive problem," said Michael Maness, Knight Foundation vice president of journalism and media innovation. "Bringing the program to more communities is a big step towards reducing prescription drug abuse, and providing people with the resources they need to take action."

About SafeUseNow℠
SafeUseNow is a risk identification and intervention program developed by Principled Strategies, a healthcare consultancy with expertise in predictive analytics, optimization, and risk analysis. The SafeUseNow advantage is 17 predictive risk factors discovered in a multi-year study of physician prescribing, pharmacy dispensing, and patient utilization of controlled substance drugs. SafeUseNow is an actionable solution for systematically and efficiently combating the misuse, abuse, addiction and diversion of controlled substance drugs.

To learn more, visit http://www.safeusenow.com and follow @safeusenow on Twitter.

About Partnership HealthPlan of California
The Partnership HealthPlan of California is a public/private organization designed to provide a cost-effective healthcare delivery system to Medi-Cal recipients in 14 Northern California counties, including Solano, Napa, Yolo, Sonoma and Marin. The HealthPlan's goals are to improve access, quality and cost effectiveness through a managed care system. The HealthPlan links each of its 455,000 members with providers from its network of 890 primary care physicians and over 2,500 medical specialists. Partnership HealthPlan has been successful in reducing inappropriate emergency room usage, delivering an appropriate level of inpatient care, developing innovative case management programs and providing more services locally. To learn more, visit http://www.partnershiphp.org.

About the Knight Foundation
Knight Foundation supports transformational ideas that promote quality journalism, advance media innovation, engage communities and foster the arts. We believe that democracy thrives when people and communities are informed and engaged. For further information, please visit: http://www.knightfoundation.org.

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![safeusenow logo]

FOR IMMEDIATE RELEASE

Contact: Patrick J. Burns, President, Principled Strategies
Tel.: (760) 230-6323 l email: patrick.burns@safeusenow.com

SafeUseNow Selected to Showcase at TEDMED Hive 2014

SafeUseNow to demonstrate how its predictive analytics can be used to identify and help mitigate prescription drug abuse risk

ENCINITAS, Calif. July 29, 2014 - What if you could stop prescription drug abuse directly at the source? That's the big public health question being addressed by SafeUseNow[SM], an innovative prescription drug abuse risk program developed by Principled Strategies. SafeUseNow has been selected from hundreds of applicants worldwide to be part of The Hive at the annual TEDMED Conference, September 10-12 in San Francisco, CA. The Hive is a community of exceptional startups and entrepreneurs powering healthcare transformation and shaping the future of medicine.

TEDMED, an affiliate of the TED organization, is a global community dedicated to unlocking imagination in service of health and medicine. The conference takes place simultaneously in Washington, DC and San Francisco, CA via a unified, digitally linked program. TEDMED features demonstrations of the best new ideas accelerating healthcare in The Hive – an immersive social environment dedicated to exploring and showcasing transformative startups and the inspiring entrepreneurs who power them.

SafeUseNow will participate in The Hive at the TEDMED San Francisco conference. Its clinically validated solution utilizes advanced data analytics and predictive modeling to identify combinations of prescribers, patients and pharmacies at risk of contributing to the prescription drug abuse problem. This actionable information enables healthcare stakeholders, including health insurance plans, self-insured companies, hospitals, pharmacy benefit managers and pharmaceutical manufacturers to teach prescribers how to treat their patients more safely and effectively. SafeUseNow also allows customers to proactively monitor prescribing patterns for early detection of changes in prescribing trends and behavior.

"Our selection to The Hive at TEDMED San Francisco is an incredible honor," said Patrick J. Burns, president of Principled Strategies. "We're thrilled to demonstrate SafeUseNow alongside other healthcare technology companies with cutting edge solutions. Our presence at TEDMED will enable thousands of leading scientists, doctors, researchers and policy experts from around the world to experience first-hand how our solution is uniquely positioned to actively combat our national prescription drug abuse epidemic."

"TEDMED is delighted to welcome SafeUseNow to The Hive, where our our multi-disciplinary, global community will experience a broad landscape of tomorrow's most exciting innovations in health and medicine," said TEDMED COO and Partner Shirley Bergin.

"In The Hive," continued Ms. Bergin, "the leaders from Safe Use Now will be part of an informal, immersive social environment where the entire TEDMED community can actively participate in the future of health and medicine in a hands-on way. Equally important, all Hive participants will help drive TEDMED's ongoing conversation about the best ways to accelerate medical progress and create a healthier life for our planet's 7 billion people."

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For further information about TEDMED and a profile of SafeUseNow, visit http://www.tedmed.com/event/the-hive#startup-item-283572.

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Company Overview

Providing a clear view of the risks and opportunities ahead.

Principled Strategies is a unique collaboration of experts in strategy, advanced analytics and economics. Our mission is to provide our clients with the intelligence and insight they need to make smarter strategic and tactical decisions.

We do this by leveraging pioneering experience in business analysis, data mining and predictive modeling. Our clients receive the ability to make decisions based on clearly defined metrics, so they can move more surely, quickly, and efficiently toward their objectives.

In today's increasingly competitive economy, organizations demand reliable solutions for exploiting data to help intelligently manage the entire product life cycle. Principled Strategies answers complex questions deeply rooted in data with superior analytical solutions.

The hallmarks of our approach are:

EXTRAORDINARY DETAIL: Through exhaustive data mining and proprietary analysis techniques, we create predictive models that not only illuminate regions and markets, but that also extend down to individual healthcare professionals and patients.

POWERFUL FOLLOW-THROUGH: Decades of experience in the life science industry allow us to go beyond providing raw intelligence. We help our clients to take strategic and tactical action with confidence.

MEASURABLE RESULTS: By enabling our clients to make smarter decisions, we help them overcome complex challenges, reduce costs, and maximize their return on investment.

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Predictive Analytics

Understand, anticipate and proactively respond

Predictive analytics is the combination of descriptive and inferential statistics. It involves gaining an accurate understanding of past business performance to draw informed conclusions about the future. As pioneers in predictive modeling, the value of our approach is taking you beyond traditional retrospective analysis and helping you anticipate and react accordingly.

Resource Optimization

Maximize the impact of every investment dollar

Optimizing your investment in key business drivers can dramatically improve profitability without requiring large-scale change to current tactics. Our data-driven optimization techniques can substantially increase the return on every resource investment dollar. Our unique approach helps unearth opportunities that result in bottom-line profits.

Risk Analysis

Develop realistic solutions

Every resource investment decision must be balanced with a real-world assessment of your business environment. Our team places great value in working with you to achieve optimal solutions that are appropriately aggressive and realistically actionable. We will provide you with alternative solutions that balance your business objectives with your risk preferences.

Principled Strategies is the developer of SafeUseNow℠, a risk identification and intervention program used by health insurance plans, pharmaceutical companies and government agencies. SafeUseNow is an actionable solution for systematically and efficiently combating the misuse, abuse, addiction and diversion of controlled substance drugs. The SafeUseNow advantage is 17 predictive risk factors discovered in a multi-year study of physician prescribing, pharmacy dispensing, and patient utilization of controlled substance drugs.

About SafeUseNow

SafeUseNow is a novel, prescriber-centric solution and risk identification and intervention program to combat the spread of prescription drug abuse. Using multiple sources of data, advanced analytics, and a patent pending risk identification model our solution enables managed care organizations to identify those whose prescribing behaviors may contribute to prescription drug abuse.

The program was developed by Principled Strategies, a health care consultancy with expertise in predictive analytics, optimization and risk analysis.

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INTELLIGENCE.insight.ILLUMINATION.

HELPING ORGANIZATIONS MAKE SMARTER DECISIONS

PRINCIPLEDstrategies

LIFE SCIENCE ANALYTICS

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UNDERSTAND, ANTICIPATE, AND PROACTIVELY RESPOND

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ANSWERS TO CRITICAL QUESTIONS:

- What risk-cost-benefit profile does a new drug candidate have?
- How can meta-analysis strengthen an NDA, and possibly avoid a costly clinical trial?
- What unexpected, measurable benefits accrue to patients in a clinical trial?
- What is the optimal price for a new drug?
- What is the impact of a price change to market share?
- What is the economic impact of a new market entrant?
- How can I accurately forecast sales?
- What budget allocation optimizes ROI?
- What is the optimal promotional mix?
- What was the average marginal return for each promotional channel?
- What sampling level is most appropriate?

CASEstudies

Marketing mix optimization
OPTIMIZING MARKETING INVESTMENT FOR A BLOCKBUSTER DRUG IMPROVES REVENUE

Class: Anti-depression
Revenue: >$1 billion
Field force size: 2,500
Physicians: 125,000
Achievable ROI: $25 million

By measuring physician response to myriad promotional and non-promotional activities and accurately forecasting physician-level prescribing behavior, optimization permits our clients to maximize their marketing mix ROI.

In this engagement our team optimized the marketing mix for nearly 125,000 target physicians in the SSRI market. Our work began by calculating physician-level promotional sensitivity to key tactics such as details, meetings and events, and professional journal and direct-to-consumer advertising. A key objective of this work was to separate collateral effects in order to expose the unique contribution made by simultaneous promotional events. We next controlled for key non-promotional effects such as disease incidence and prevalence, seasonality, and census markers. Then, using a scenario builder we considered thousands of possible marketing mix allocations, each one resulting in a forecast of total prescriptions in the SSRI market for both our client's brand and competitor brands. The scenario builder included a dynamic market forecast component that predicted competitor responses to each proposed change in our client's marketing mix, thereby providing our client with a clear, short-term view of the competitive landscape.

The result? Our client deployed the tool in their periodic POA process so that Sales and Marketing leadership could explore, in real-time, the resulting ROI of each level of promotional investment considered. Optimizing the marketing mix at a physician-level unearthed achievable ROI of $25 million.

Clinical trials meta-analysis
SECURING E.U. REGISTRATION FOR A CANCER TREATMENT AVERTS A COSTLY CLINICAL TRIAL

Class: Anti-cancer
Revenue: <$1 billion
Patients: 5,000
Achievable ROI: $15–$75 million

In preparation for filing for product registration in the European Union, a prominent oncology research group sought to compare the efficacy, toxicity, and safety profiles for its drug versus those whose results were published in leading clinical research journals. The drug was already approved for use in the United States and had a randomized controlled trial underway, but the client did not expect results for another eight years.

Our work involved culling through more than 2,000 journal articles in order to develop a comparator database of published clinical trial results. We then compared published results for key endpoints to those in the client's clinical studies: complete remission rate, median relapse-free survival, and overall survival. Finally, we reported statistically validated measures of superiority and inferiority across all key dimensions.

Our meta-analysis report was submitted with the client's product registration filing as evidence of results likely to emerge from the randomized controlled trial. Should the EU approve the product registration in its current form, the client will avert a costly clinical trial and launch its drug five years sooner than originally planned.

With the drug's EU revenue projected to average $15 million per year, the achievable ROI for this client is conservatively in the range of $15–$75 million.

Program ROI validation

VALIDATING A MARKETING OPTIMIZATION PROGRAM ENSURES MAXIMUM ACHIEVABLE R.O.I.

Class: Sedatives

Revenue: >$1 billion

Field force size: 2,000

Physicians: 100,000

Achievable ROI: $30 million

A marketing optimization program should be evaluated in terms of its ROI. Planning, implementation, and validation in support of an optimization program ensures maximum total return. In a recent engagement, a Principled Strategies team completed a marketing optimization validation analysis.

The methodology measured one-year effectiveness for key physician-level programs. Our analysis compared the behavior of a control group of physicians to a test group of physicians in order to identify both successes and failures. The study resulted in an ROI estimate for each physician, and precisely accounted for sales representative adherence, the largest individual contributor to program ROI. Using a principled validation methodology, the team successfully measured total ROI, physician ROI, key contributors to physician ROI, and channels for which the client can improve program effectiveness.

The results offered immediate feedback that permitted the client to react and respond to groups of suboptimally performing physicians. A tangential benefit of the project was an improved understanding of techniques for securing sales representative buy-in. The tangible benefits for this client include enhanced knowledge, improved capture rate for achievable ROI, and more efficient planning and marketing in the future.

Quality of care analysis for health plans

DATA MINING OF COMPLICATION RATES REVEALS OPPORTUNITY TO IMPROVE PATIENT CARE

Therapy: Bariatric surgery (obesity)

Revenue: $225 million

Patients: 9,300

Achievable ROI: $15 million over two years

A prominent BlueCross® BlueShield® company commissioned a quality of care analysis for the treatment of morbid obesity. Aggregate treatment costs for bariatric surgery were growing faster than projected, and complication rates began to rise. As the treatable patient population was expected to grow by 65% within 10 years, management sought to better understand the relationship between quality of care (QOC) and bottom-line performance.

Four study objectives were identified:

1. Compare common recurring surgical costs.
2. Evaluate hospitals and physicians.
3. Analyze complication costs.
4. Demonstrate achievable savings by comparing patient costs to a benchmark measure.

Using data mining and statistical analysis techniques, an estimate of achievable cost savings that would result from improved patient QOC was developed.

The result? An achievable ROI of $15 million over two years for employing a bariatric surgery Centers of Excellence program.

Heart attack and stroke prediction

USING M.R.I. IN CARDIOVASCULAR DISEASE MANAGEMENT TO MEASURE PLAQUE BURDEN

Diagnostic: Vulnerable plaque burden

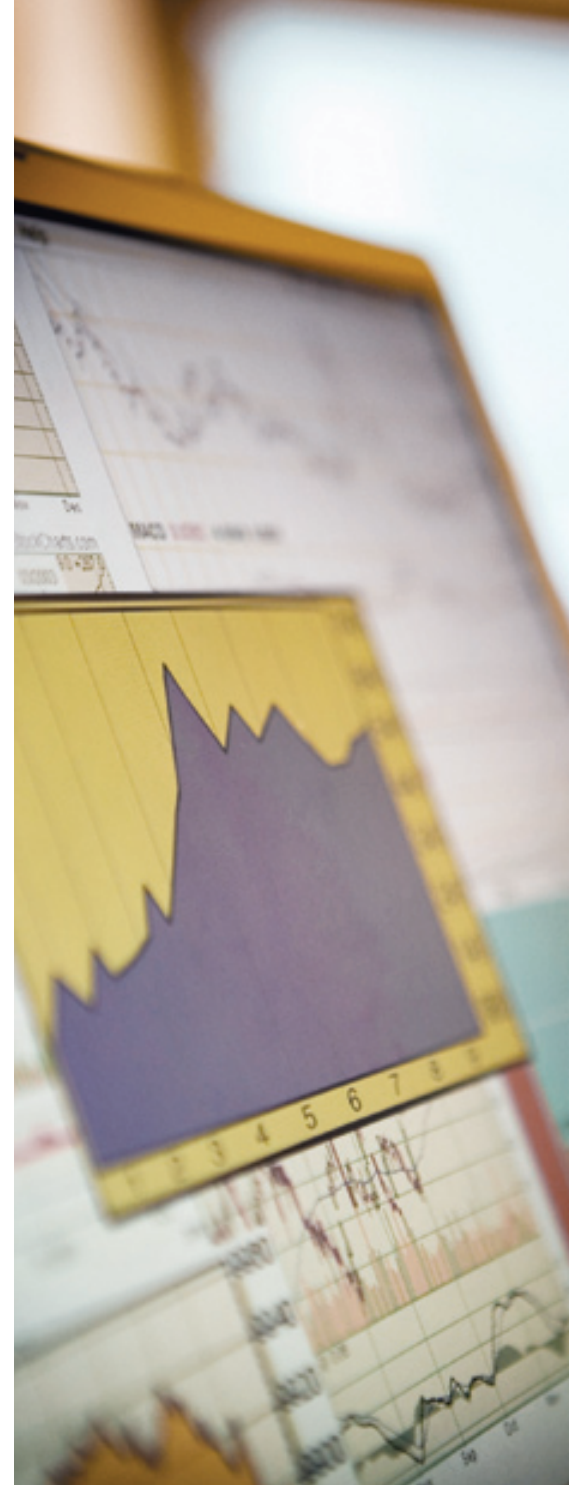**Revenue:** >$100 million (annual projected)

Patients: >500,000 (annual projected)

Achievable ROI: $90 million

An early stage bioinformatics company sought to develop a medical product to noninvasively detect the presence of vulnerable plaque— a type of plaque that can rupture and result in heart attack or stroke. Astoundingly, death is the first sign of cardiovascular disease in 40% of all reported cases in the US. With 70% of heart attacks resulting from plaque rupture in areas containing little plaque, current diagnostic methods proved incapable of reliably detecting high-risk vulnerable plaque. Consequently, research and development began to design a product to resolve this critically unmet need.

Product prototyping began with the construction of a plaque burden prediction model. The data used for development of the prediction model originated in the MRI of both in vivo and ex vivo patients diagnosed with cardiovascular disease.

How does this product work? By applying proprietary analytical and statistical methods to outcome data from landmark studies, we improved the ability to predict plaque burden for high-risk patients. Now, millions of patient lives can be extended through lower cost, first line interventional treatments, potentially saving the healthcare system hundreds of millions of dollars each year.

Patrick J. Burns
President/CEO

Mr. Burns is the President and CEO of Principled Strategies. He has more than 20 years of experience as an executive and consultant in the public and private sectors. He specializes in strategic planning for product development and product commercialization initiatives using advanced data analysis and decision support systems. Mr. Burns has successfully designed and directed the analysis and optimization of hundreds of clinical and commercialization programs for dozens of FORTUNE 1000 companies.

Since 2009 Mr. Burns has directed the research and development program responsible for development of the SafeUseNow℠ program, including its recently completed three-year clinical trial.

Areas of expertise
- Strategic planning and corporate development for product development and commercialization initiatives
- Predictive analysis, resource optimization, and risk analysis
- Data mining, executive information, and decision support systems
- R&D for scientific and health care information technology applications

The Darden School Executive Education, University of Virginia; B.S., Business Administration with Finance and Economics concentrations, San Diego State University

Contact Information:

Patrick J. Burns
Principled Strategies, Inc.
179 Calle Magdalena, Suite 200
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David Schuster
Advisor

Mr. Schuster is a serial entrepreneur with over 20 years of experience in healthcare and technology startups. He possesses solid strategic management and corporate development experience in the software development, mobile application development, and web industries.

He has spent the last decade working domestically and internationally developing strategies, partnerships and fundraising programs for both startup and NASDAQ organizations.

Mr. Schuster is the co-founder and CEO of NudgeRx, Inc., a healthcare IT company focused on preventing hospital readmissions using web, mobile and nursing services to monitor and manage patients after being discharged from the hospital. NudgeRx has had a very successful IRB approved study/pilot program exceeding the expected improvements in patient care and cost reduction at the pilot site.

Prior to launching NudgeRx, he was Managing Director of Galt Strategy, LLC where he worked as a consultant helping build concierge healthcare and addiction treatment programs and services. In this role he helped doctors and other treatment providers define their business models, launch companies, and establish procedures for controlling expenses. Before Galt, Mr. Schuster was the VP of Corporate Development at Hythiam, Inc. where he was responsible for developing and launching Hythiam's "Catasys" disease management program, establishing the international operations, and building the company-managed multidisciplinary treatment center. Earlier, Mr. Schuster was one of the initial employees at LifeMaster Supportive Selfcare, a pioneering company in disease management.

BS, Business Administration; Marquette University

Contact Information:

David Schuster
Principled Strategies, Inc.
179 Calle Magdalena, Suite 200
Encinitas, CA 92024
david.schuster@safeusenow.com
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Paul DuBose, PhD
Vice President, Analytics

Dr. DuBose is one of the industry's most respected analysts. He leads a team of experts that provides clients with sophisticated solutions and insights to highly quantitative problems through a synergy of advanced analytics and extensive industry experience.

Dr. DuBose has patented algorithms and developed trade secret methodologies years ahead of commonly available statistical techniques; created analytical processes to rapidly and cost effectively develop customized, sophisticated predictive models; and performed ground-breaking work in Artificial Neural Networks (ANNs) leading to seminal research in process control.

He has over fifteen years of experience in modeling promotional response and optimally allocating promotional resources. Dr. DuBose has worked with pharmaceutical companies in Asia and Europe as well as the United States and has developed promotional response models for numerous products in a wide range of therapeutic classes. Prior to joining Principled Strategies and co-founding SafeUseNow℠ he worked at a major pharmaceutical company.

Ph.D. and M.S., Statistics, Iowa State University; M.S. Software Engineering, Seattle University; M.S. and B.S., Mathematics, Portland State University

Contact Information:

Paul DuBose, PhD
Vice President, Analytics
Principled Strategies, Inc.
179 Calle Magdalena, Suite 200
Encinitas, CA 92024
760-230-6324
paul.dubose@safeusenow.com
www.safeusenow.com

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Lawrence Feinstein, PhD
Vice President, Clinical Programs

Dr. Feinstein is the architect of the innovative SafeUseNow℠ prescriber and patient prescription drug abuse intervention program.

Dr. Feinstein previously was Vice President of Product Development at OptumHealth where he developed programs in behavioral health and medical-behavioral integration. His expertise in program development includes six years as a Solutions Director at Fair Isaac Corporation (FICO) where he adapted advanced analytics, data management, and decision technology to create health care solutions. His experience includes software development and product management for behavioral health managed care organizations, community clinics, and individual providers.

Dr. Feinstein currently has a private practice near San Francisco where he helps people with chronic medical conditions manage their health and treatment. He also assists care-givers with stress, coping, and life balance. Dr. Feinstein received postdoctoral training at UC Irvine Medical Center.

Ph.D. Psychology (Behavioral Health); UCLA

Contact Information:

Lawrence Feinstein, PhD
Vice President, Clinical Programs
Principled Strategies, Inc.
179 Calle Magdalena, Suite 200
Encinitas, CA 92024
760-230-6320 x326
lawrence.feinstein@safeusenow.com
www.safeusenow.com

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About SafeUseNow

SafeUseNow is a novel, prescriber-centric solution and risk identification and intervention program to combat the spread of prescription drug abuse. Using multiple sources of data, advanced analytics, and a patent pending risk identification model our solution enables managed care organizations to identify those whose prescribing behaviors may contribute to prescription drug abuse.

The program was developed by Principled Strategies, a health care consultancy with expertise in predictive analytics, optimization and risk analysis.

About Principled Strategies

Principled Strategies leverages the power of predictive analytics, optimization, and risk analysis to create innovative, customized solutions that significantly improve our clients' performance.

Principled Strategies specializes in key aspects to optimizing healthcare, including strategy, advanced analytics, and economics.

For more information, please contact:

Patrick J. Burns
President/CEO
Principled Strategies, Inc.
179 Calle Magdalena, Suite 200
Encinitas, CA 92024
760-230-6323
patrick.burns@safeusenow.com
www.safeusenow.com

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