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Information on the Speaker

The speaker is co-inventor of some of the most advanced electronic dashboards for the management of electronic clinical trials, and a Former 2nd-in-command of the US FDA, where he, with FDA Commissioner, Dr. Frank Young, co-led the last major reform of the FDA.

12/10/2012

Farming Complex Adaptive Systems (CASs) Soil to Cut Healthcare Costs Ten-Fold: Advice to Platform-Company Leaders, Who Want to Optimize Their Company's High-End BI and Analytics Offerings, to Life-Sciences and Healthcare Customers

Identifying <u>Where</u> and <u>How</u> a Platform-Company's BI Platform (and Other Platforms), and Related Analytics Applications, Including Predictive-Analytics and Text-Analytics, Might Benefit from Newly Available "Best-of-Breed" High-End Analytics Technologies

By

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Complex Adaptive Systems 2012 Conference, Washington Dulles Airport

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#### **Rooms Within Rooms**



#### Wise People at the US White House



12/10/2012

#### Wise People at the US Congress



#### Wise People from US History



# Not an Exact Science/Medicine/Healthcare/IT



#### Disclaimers

- I was one of the pioneers in the HMO movement that was supposed to bring us far lower-cost healthcare and far more preventive-healthcare. I failed miserably.
- I was one of the pioneers in the hospital M&A, Systems, and Shared Systems Organization movement that was supposed to bring us far lower-cost healthcare and again far more preventive-healthcare. I again failed miserably.
- I consider this "fair warning."
- My ideas have been characterized by Haden Land as "seductive."

#### How We Can Regroup



#### Preface

• The current healthcare situation in America is poor:

- America spends 17% of our G.D.P. (some \$7,500 per American) per year on health care. (We were at just 7% two decades ago.)
- That's 50% more than any other industrialized nation
- Yet, the quality of care we get has fallen to embarrassing lows
- According to the World Health Organization, our healthcare delivery system ranks 37th in overall quality, between Costa Rica and Slovenia
- We rank 41st in infant-mortality, alongside Slovakia and Serbia, and last among 19 leading industrialized countries in preventable deaths
- Nearly two-thirds of personal bankruptcies in the U.S. are caused by illness, yet more than three-quarters of these had health insurance
- We can and must do far better—now!!!!!
- Prevention of the next "World War" might depend on our doing so!!!!!

# Part One of My Prescription for "True Healthcare Reform"

- "Obamacare" is largely "Health-Insurance Reform"
- "True Healthcare Reform" consists of:
  - Three types of healthcare delivery system reform
  - Healthcare regulation reform
  - Healthcare-IT reform

#### Three-Legged Stool

**Massive Personalized-Medicine-Reform** 

**Massive FDA-Reform** 

Massive Upward-Spiral in Innovation



Massive Healthcare-IT-Reform

#### Second Three-Legged Stool

**Molecular-Diagnostic-Analytics** 

**Digital-Imaging-Analytics** 

Massive Upward-Spiral in Integrated Healthcare

lytics

Electronic-Health-Record-Analytics

# Quick Summary of What I Mean Thus Far

- Thus far, what I am talking about is:
  - The Worldwide Need
  - for Major Healthcare Innovation
  - at All Key Levels,
  - to Cut the Cost of Healthcare
  - Some Ten-Fold
  - and Thereby Vastly Improve
  - Access to
  - High-Quality,
  - Collaborative,
  - Personalized,
  - Patient-Oriented, and
  - Outcomes-Oriented Care

# Industry-Led "True Reform of the US Healthcare Delivery System"



### Industry-Led True Reform

- Under both the Big Data and the Computational Intelligence categories, the speaker (me), who is experienced in healthcarereform/healthcare-IT-reform (having led or co-led the reform of three government agencies, including the US FDA) will call on the leaders of Big-Data-platform-companies, such as IBM, SAS, GE, and Lockheed Martin, to embrace the use of "new best-of-breed highend Analytics" on their healthcare BI platforms.
- Such use would, in the speaker's (my) vision, greatly benefit both the platform companies and the nation. This is so because it would, first, "modernize" the platforms, and it would, second, also represent a first bold step forward in moving the US meaningfully in the direction of "true healthcare-delivery-system reform."
- In the speaker's (my) vision such "full and truly integrated" reform would largely be based on healthcare-IT reform—one bold step at a time, taken at least annually over the balance of the decade.

# Industry-Led True Reform (Cont.)

- The <u>Where</u>, the <u>How</u>, and the <u>Why</u> of preemptive moves by platform-companies in this direction of Big Data best-of-breed high-end Analytics will be identified and then explored.
- Such preemptive moves will be made based on the modern corporate and social philosophy that it is best for smart companies to "do good, while doing well—and vice versa."
- Under this philosophy, the "benign hand of healthy competition, altruism, and national pride and loyalty" would be used to advance both the company's key goals and the nation's complimentary key goals—at the same time. (Adam Smith, <u>Wealth of Nations</u>)
- "Candidate best-of-breed high-end Analytics engines" for driving key elements of this reform initiative will be identified.

# Industry-Led True Reform (Cont.)

• Finally, selected analytics for performing:

- (A) very precise and thoughtful "text analytics of all <u>unstructured</u> text sources," such as (1) emails, (2) voice-mails, and (3) physicians', nurses', and technicians' notes posted to EMRs by the trillions, and
- (B) "predictive analytics" deep mining and high-end, advanced analyses of (1) EMR-based data, (2) Internet-based data, and (3) clinical-trials-report-based data, as well as (4) streaming data from healthcare remote sensors, monitors, and other medical devices/machines, for example—
- to support semi-automated or automated decision support, or new drug discovery, development, or FDA-approval "medicalknowledge-processing and advanced clinical trials," or "robotic surgery" (Summit Technology), or "robotic diag" for example—
- will be identified, explained, and critiqued.

#### **Complex Adaptive Systems**



# Complex Adaptive Systems (CASs)

- "Complex adaptive systems" (CASs) are special cases of "complex systems."
- They are important to the future of healthcare.
- The human body, its organ systems, its individual organs, its cells, and its DNA, as well as "precise models" of these items, are all CASs.
- CASs are formed in order to "adapt" to changing environments, and thereby increase survivability or management and control.
- CASs represent an emerging suite of technologies that aim at producing science-interconnections and science-architectures that exhibit "autonomic learning and adaptive capabilities."
- CAS technologies, while still evolving, have already provided capabilities for discovering "patterns" in large amounts of data-base-sourced or sensor-sourced "actionable data/information/insights/knowledge/ wisdom/intelligence" (e.g., offline learning, and data mining).

- CAS technologies have also proven capable at "statistical learning theories," which are frameworks for machine learning—drawn from the fields of statistics and functional analysis.
- This is the theoretical framework underlying "support vector machines," SVMs, which we will highlight later.
- SVMs are a set of related supervised learning methods that analyze data and "recognize patterns," used for such applications as computer vision, speech recognition, and bioinformatics.
- Finally, CAS technologies have proven capable at "heuristics" (a trial-and-error mathematical method of problem solving used when an algorithmic approach is impractical) for supporting reliable inferences from these found patterns.

- An important facet of "Complexity Science" deals within key domains, such as Healthcare.
- Within the healthcare arena there is structured or unstructured:
  - (1) machine based or generated data
  - (2) sensory inputs from many biologic sources, such as remote or bed-side sensors and monitors, and
  - (3) written or dictated-voice information based upon practitioner note entries in EMRs/EHRs
- Most of this data is disparate and "un-relatable" in that it is difficult to use to provide "meaningful trends analyses" and historical analytics that can predict appropriate and/or most-appropriate "next step" treatments.

- This effort is aimed at developing focused research and analysis that will strive to provide key innovative applications that Platform Companies might consider when planning their strategies for product developments in key domains, such as healthcare:
  - (1) organizational/operating business models,
  - (2) patient-evaluation/care-delivery business models, and

- (3) incentives/financing business models—

systemization/integration and innovation/automation, where combining CAS technologies might provide new and valuable capabilities.

 The intent of our effort is to include ideas that span a range of times-to-market, from opportunities that could be realized in 3-5 years and require no heavy research and no technology breakthroughs, to opportunities that may be years from practical realization, but that are sufficiently exciting and near-feasible to help guide near-term and long-term R&D investments by Platform Companies.

#### A Bridge to Somewhere



# Imagine

- Imagine how much more "actionable-healthcare-intelligence" a platform-company's life-sciences and healthcare customers could gather from using that company's business intelligence platform (and other platforms) to manage optimally complex adaptive systems (CASs),
- if the platform(s) offered "far faster, cheaper, better and safer," "best-of-breed," high-end analytics—enabling the customers (1) to glean new, highly valuable insights about their industry and their clients' or patients' needs and problems/solutions, and (2) to optimize their product or service strategy and efficiency/efficacy .....

#### Another Bridge to Somewhere



# What an Support Vector Machine (SVM) Is

- An SVM is a very powerful machine-learning and patternrecognition tool.
- SVMs work like very sophisticated neural nets, only, for most applications, better.
- SVMs offer so much more potential for CASs than neural nets. For example, they have the following capabilities that neural nets lack. The ability:
  - To handle very-large-size databases
  - To handle infinite varieties of data
  - To handle infinite dimensions of data analysis

### The Role of SVMs

- Newly available "advanced-analytics technologies" exist but are relatively unknown within the realm of advanced patternrecognition and machine-learning technologies.
- Among the most powerful but relatively unknown are Support Vector Machines (SVMs) and Support Vector Machine-Recursive Feature Elimination (SVM-RFE) engines.
- These new "best-of-breed" analytics engines can significantly upgrade analytics capabilities, and related features and businessanalytic functions of two key assets.
- First, they can enhance a platform-company's "Business Intelligence (BI) platform" (and other on-line or off-line platforms), and
- Second, they can enhance the "software applications" the company employs on computing platforms—to produce "intelligence-gold."

#### **Presentation Goals**

- This presentation has three key goals. To:
  - Identify the who, what, where, when, how, and why of the Norris Strategy for capturing long-term the opportunity to service and support the extremely valuable HC-IT industry, world-wide, especially in the category of managing CASs
  - Identify and clarify the precise "best-of-breed" recipe for doing this
  - Identify and clarify who benefits, if the recipe is carefully and closely followed during execution

# Key Terminology

- Key Players
  - "Smart" analytics companies
  - "Smart" platform companies
  - "Smart" life-sciences and healthcare companies
- Key Technologies
  - "Best-of breed" advanced analytics technologies
  - Advanced platform technologies
  - Advanced applications technologies

# Key Terminology (Cont.)

- Key Intermediary Products
  - Data, information, insights, knowledge, wisdom, and intelligence
  - "Actionable-healthcare-intelligence"
- Key Processes
  - Analytics
- Key Final Products
  - New or vastly improved drugs, devices, and procedures, that are faster, better, or cheaper

# Key Terminology (Cont.)

- Key Substantive Categories:
  - (1) substantive-patient-care,
  - (2) technical-patient-care-supportive,
  - (3) operational-business-compliance,
  - (4) operational-government-compliance,
  - (5) financial/billing,

# Objectives: Prosperity, Health, and Happiness



Key Examples of Analytics Technologies for Creating "Super-Analytics" Apps in CAS Settings

- Neural nets
- Linear-regression products
- SVM and SVM-RFE "best-of-breed" technologies

#### Rewards

- All three "smart" players benefit greatly both in the near-term and in the long-term, in terms of profits, market-share, and employee morale
- If they play the "game" right they not only preempt their possible competitors, they lock them out for decades, while they, of course, "ride the gravy train"
- They also create many societal benefits for patients, for communities, and for providers
#### Massive Engines/Machines of Change



## Examples of "Advantages of SVMs" Over Other CAS-Creators and/or CAS-Drivers

- CASs created and/or driven by SVMs and SVM-RFEs can:
  - More capably handle machine-learning tasks
  - More capably handle pattern-recognition tasks
  - Handle millions of variables, not dozens
  - Handle real-time work
  - State they are viewed favorably by the top researchers at the top schools (e.g., Harvard, MIT, Cornell, and Rochester) and at the top platform companies (e.g., GE, SAS, LM, Microsoft, and IBM)

# "Advantages of SVMs" (Cont.)

- Eliminate gross sampling and other resource-intensive tasks
- Work faster, more flexibly, and more precisely
- Handle large loads of different types of data quickly converting them faster, better, cheaper, and safer into truly "actionable-healthcare-intelligence"
- Address and fill/solve world-class needs/problems

- Support new or vastly improved features/functions, especially "more and more robust text-analytics," a critical component of all future CASs
- Be employed to solve nano/micro problems or mega problems
- Be employed to automate/roboticize small or large machines or systems
- Be employed to reap cost-reductions at the unit, enterprise, system, nation, or world levels

#### **Partnering for Success**



#### Ways to "Partner"

- There are three possible ways to "partner" between the three "smart" participants. The platform developer and the lifesciences company can:
  - License the technology from the analytics company
  - Partner with the analytics company (50/50; 60/40)
  - Acquire the analytics company

#### Key Examples of What I Speak



## Key Examples of "Unstructured Data Sources" to be Digested by the Robust Text-Analytics Engine

- Relevant unstructured-data sources to be targeted might include:
  - Articles
  - Videos
  - Audios
  - Emails
  - Voicemails
  - Social-web postings
  - EMR physicians', nurses', and technicians' notes or other postings
  - And the like

## Key Examples of "Medical Machines" Created and/or Driven Using SVMs

- Key examples of current and/or developmental "Medical Machines" include the following:
  - (1) Regrettably, the identity and the detailed features of this application are STRICTLY CONFIDENTIAL
  - (2) Regrettably, the identity and the detailed features of this application are STRICTLY CONFIDENTIAL
  - (3) Regrettably, the identity and the detailed features of this application are STRICTLY CONFIDENTIAL
  - (4) SVM-Machine for FDA-acceptable MKP and CT, under current or future models
  - (5) SVM-Machine for FDA-acceptable Cytogenic 2<sup>nd</sup> opinions
  - (6) SVM-Machine for FDA-acceptable PCA 1<sup>st</sup> and 2<sup>nd</sup> opinions

## Key Examples of "Medical Machines" (Cont.)

- (7) Field-Hardened Flow Cytometry Machines, for detecting or predicting onset of sepsis, dynamically, for example
- (8) Robotic Surgery Machines, ala Summit Technologies automated laser-eye-surgery (LASIK) machines
- (9) Hospital System Cost-Reduction Machine
- (10) A \$1 Machine for Early Detection of Melanoma (the MelApp for iPhone use)
- (11) New Machines to "convert healthcare's descriptive models to predictive models"
- (12) Many other "disruptive machines"

## Using SVMs to Create and to Drive FDA-Acceptable MKP-Machines and CT-Machines



#### Four FDA Phases of Drug Development

Phase	Phase 2	Phase 3	Phase 4
1		Safety	Post
Safety	Safety	And	Market
	And	Efficacy	studies
	Efficacy	Fast	
20-40	200-400	Track	2,000-
		2,000-	5,000
		5,000	

#### Relative Success of Clinical Research (NCEs Submitting First INDs in 1976-1978)



#### The Costs Are Incredible



## SVM-Created Cytogenetic 2<sup>nd</sup> Opinion App



🛃 Cytogenetic Reader			
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#### SVM-Created Blood-Plasma-Based Prostate Cancer Testing



#### **SVM-Created Plasma-Based Testing**

Tumor cells:

-Have high turnover

-Pour their debris into blood.

Plasma is <u>enriched</u> by tumor-specific DNA, RNA and proteins.

Most of cell-based tests can be performed using plasma

#### Comparing PCA3 with the 4-Genes in Plasma-Based PCA Testing

	<u>Sensitivity</u>	<u>Specificity</u>
<u>PCA3</u>	43%	83%
<u>4-Genes</u>	67%	100%

More specimens are needed for the developing of new algorithm for the 4-genes

### Other Examples of Potential New SVM-Created and/or SVM-Driven Machines



## Key Examples of SVM-Created and/or SVM-Driven "Supportive-Adjuncts to Medical Machines"

- Increasingly included, as "supportive" adjuncts to, and as both structured and <u>unstructured</u> data-sources for, these key new or vastly improved patient-care devices (machines), are wired and wireless automated:
  - Sensors
  - Monitors
  - Care coordinators and care dispensers
  - Video-and-still-cameras
  - Floor-mounted and hand-held XRAY imaging-machines
  - Radiology and pathology laboratory devices (such as NMR machines and flow-cytometry-platform devices), and
  - Other mega-data-producing devices (such as secure, accurate, and reliable patient identification devices)

#### **Desirable Features**



## Key Examples of "Desirable Features and Business-Functions" that Might be Enabled by SVMs

- These technologies have untapped powers that we are only beginning to understand. They will enable BI platform companies, and their life-sciences and healthcare customers, to achieve far faster, better, cheaper, and safer "data processing."
- But they will also enable them to add three very desirable new "feature sets" into three BI categories: (1) advanced text-analytics, (2) advanced security, and (3) advanced predictive-analytics.
- They also add value to key "business-functions" on their BI platforms, such as, (1) advanced business-process-automation, (2) advanced business-activity-monitoring, and (3) advanced executive-information-automation.
- These new features and functions make the BI platforms and the software applications they use, both "operationally better" (i.e., "faster, better, cheaper, and safer") and "functionally better" (i.e., "smarter, deeper, broader, more-granular, and more-robust").

#### More Key Features and Functions



## More Examples of Possible "Advanced Key Features and Functions" that Might be Enabled by SVMs

- Advanced key features and business-functions covered by these additional patient-care/supportive applications include, for example, the use by lifesciences and healthcare customers of advanced:
  - Business-process-management (BPM)
  - Data-mining
  - Data-warehousing
  - Business-process-automation
  - Decision-support-automation
  - Query-and-reporting-automation
  - Enterprise-performance-management
  - Executive-information-automation (EIA)
  - Business-activity-monitoring (BAM)
  - Modeling-and-visualization
  - To name just a few

#### **Other Benefits**



## Key Examples of "Other Benefits" that Might be Enabled by SVMs

- Results:
  - of applying the advanced AI and pattern-recognition technologies ....
  - to smartly and appropriately create, enhance, drive, measure, correct, and use ....
  - some of the highly beneficial and productive applications that are now critically needed and being invented—in (1) science/medicine, (2) genomics, (3) proteomics, (4) diagnostics, and (5) drug discovery

#### **Advanced Key Features and Functions**



#### Patient-Care "Automation Applications" that Might be Enabled by SVMs

- High on the list of novel and robust life-sciences and healthcare companies' patient-care "automation applications" that might be created, are:
  - Automated "personalized medicine applications" (including genetics-based diagnostics and "companion diagnostics"),
  - Automated "medical-knowledge-processing-based newdrug-discovery" applications (using outcomes-valuefocused, internet-based, and text-analytics-based, searches and collections of—and high-end analyses of the scientific and medical literature, and sets of assembled and de-identified EMR data), and

## Patient-Care "Automation Apps" (Cont.)

- Robotically automated "medicine, pathology, radiology, and surgery procedures applications," including:
  - (1) tele-health applications
  - (2) EKG monitoring, analyzing, and reading applications
  - (3) electronic-ICU applications, and
  - (4) robotic surgery of the eye (LASIK) and of the brain
- Here, it should be noted, the focus is on using "insights-tocreate-beneficial-outcomes" (i2CBOs), meaning that, like in the use of catalysts to drive chemical reactions, small insights are created that have massive impacts on the speed, number, size, cost (both marginal-cost, and incremental-cost), and quality of meaningful, agile, and highly granular, as well as precise and adaptive, beneficial-outcomes, which of course, are our key final objectives.

#### Advanced Real-Time Compliance Apps



# Possible "Advanced Real-Time Compliance Apps" that Might be SVM-Enabled

- Five advanced "real-time compliance applications" come immediately to mind.
- For example, automated, "real-time FDA-CDC-IRS-and-NIH-compliance" applications might be very beneficial.
  - They might be developed by possibly using a "combined compliance, quality-management, and BI platform"—
  - that monitors and manages, on a high-performance, low-cost, and agile BI and BA architecture and application basis, bottom-up operational-parameters—
  - and also, simultaneously, monitors and manages top-down riskparameters and cost-parameters,
  - as well as overall ROI from allocated resources.
- Such a complex platform-application combination might possibly be created, and then be used on an automated basis, to maximize benefits.

- For a second example, automated "EMR-based real-time clinical trials applications" (using: (1) doctors, (2) patients, and (3) EMRs, rather than far-more-expensive, and far-slower: (1) investigators, (2) subjects, and (3) clinical-trials reports).
  - These might be used to chop tens, or even hundreds, of millions of dollars off of the Billion-dollar-plus cost of conducting clinical trials required for obtaining FDAapproved US market access for new drugs or new devices.

- Additional examples of other possibly useful advanced compliance-applications include the following.
- At the near end of the range, the new advanced complianceapplications might enable life-sciences and healthcare customers to use very advanced predictive-analytics applications:
  - (1) for projecting future price-elasticity of, and future aggregatedemand for, raw-materials, supplies, or finished- goods or deliveredservices
  - (2) for identifying, establishing, and controlling mandated (such as by the FDA) or required (such as by the customers' banks) key economic, legal, and regulatory risk-management strategies, and
  - (3) for completing associated key risk-management tasks, for example.

- In the middle of the range, by using the combined high-end analytics tools, systems, and technologies, on a platformcompany's right platforms, the life-sciences customers might be better able to perform "creative work" involving:
  - (1) key forecasting, budgeting, and planning applications
  - (2) other high-end predictive-analytics applications, such as might be used in key marketing and sales, patient-adherence, and patient-billing/accounts-receivable-collection initiatives, and
  - (3) other key BI and high-end real-time analytics applications, such as applications capable of \$ Trillion real-time fraud prevention, for or by Medicare, Medicaid, private-healthinsurers, and fully or partially self-insured hospital systems, for example, which is especially important.

- At the far end of the range, the combined use of the advanced-analytics technologies, methods, and products on the right robust platform—to create high-end advancedanalytics applications—might enable life-sciences and healthcare customers to use, or create and use, robust applications for automating fully some of their other tools, systems, and platforms, or even enterprises.
- Here, in one of the most advanced such uses, for fullenterprise automation, for example, which might not be ready for full use for a decade, machine-data-driven robotic applications might work very productively.
### Conclusions



#### Conclusions

- Thus, joining these right "best-of-breed" advanced-analytics technologies with the right platforms and the right customers might enable all of the "smart-participants" to sustain their competitive advantages in CASs for years, and perhaps even decades, to come—a real "win-win-win-win-win-win."
- Together, they might create a "strangle-hold on," and both broadly and long-term, "effectively dominate," a niche market in CAS applications that is essential to the profitable growth of the world's key life-sciences and healthcare companies—and to these companies own corporate, group, and individual customers/patients—over time.

# Conclusions (Cont.)

- This dominance might, in turn, enable the "smart participants" to jointly and brilliantly shape the responsible adoption, by the rest of the world's key life-sciences and healthcare companies, of creative new and evolving, veryvaluable enhancements, innovations, or inventions to these platforms and advanced-analytics technologies in CAS applications.
- Included here might be the joint advanced platforms and applications described here above.
- But, interestingly and most excitingly, it also might possibly include those totally new technologies, platforms, and applications that might be newly envisioned and invented in coming decades, in an upward spiral of science/medicine/IT.

## Conclusions (Cont.)

- And all of these tools, methods, platforms, and technologies, both new and old, and of course their children, and grand children, might possibly be customized, enhanced, or re-invented, for optimal use on advanced new or vastly improved Cloud Platforms and on advanced new or vastly improved Big-Data Platforms—or on other key new or vastly improved platforms that might also be envisioned and invented in coming decades.
- Together, these "smart participants" might thereby be able to become (and to steadfastly remain) "top-dog-dominant," and "firstmover-disruptive," as well as "much-trusted-and reliable," "best-ofbreed" technology enhancers, innovators, and inventers—over the very long-term, to everyone's benefit—manufacturer, provider, payer, employer, patient, and patient-family, alike.

## Conclusions (Cont.)

• Finally, these inventions and their brethren, commercialized innovations, will help us to realize, to realize by the end of this decade, or at the latest, the next, my goal of cutting the cost of healthcare (in today's dollars) by ten-fold.

### Further Information



# The End

- Brief Bio:
  - John A. Norris, JD, MBA, is (1) a former second-in-command of the US FDA (where he co-led the last major reform of that storied agency), (2) a former Harvard faculty member, the co-leader of the Billion-dollar turnaround of the inventor of automated laser eye surgery (LASIK), Summit Technology, (3) the founder and former faculty-editor-in-chief of <u>The American Journal of Law and Medicine</u>, and (4) an officer and/or board member at numerous highly creative companies or organizations. He is also (5) a philanthropist, and (6) a founder of more than a dozen companies or organizations.
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#### Yet to be Inserted Slides