

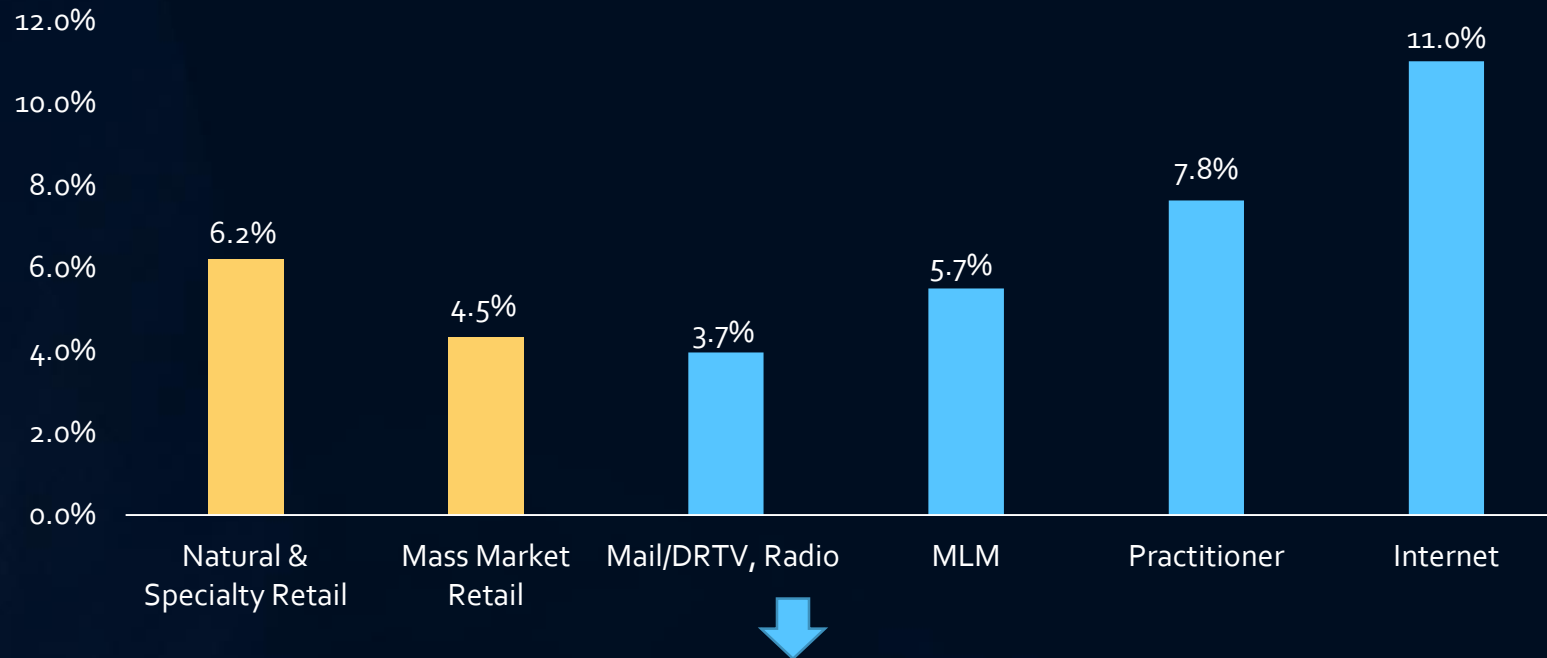
# Practitioner Channel Update

UNPA MEMBERS RETREAT, MAY 2017

# Integrative Medicine Era

- The Trailblazing Years
  - DSHEA
  - NCCAM (National Center for Complementary and Alternative Medicine)
  - Wave of physician education on Complimentary or Alternative Medicine (CAM)
- A New Identity
  - From “quackery” to relevant for topics such as microbiome, leaky gut, adrenal fatigue etc.
  - From fringe to recommended for dietary supplements, even in mainstream medicine
  - Emergence of influential research centers and holistic options among leading healthcare institutions

# US Supplement Sales Growth by Channel in 2016



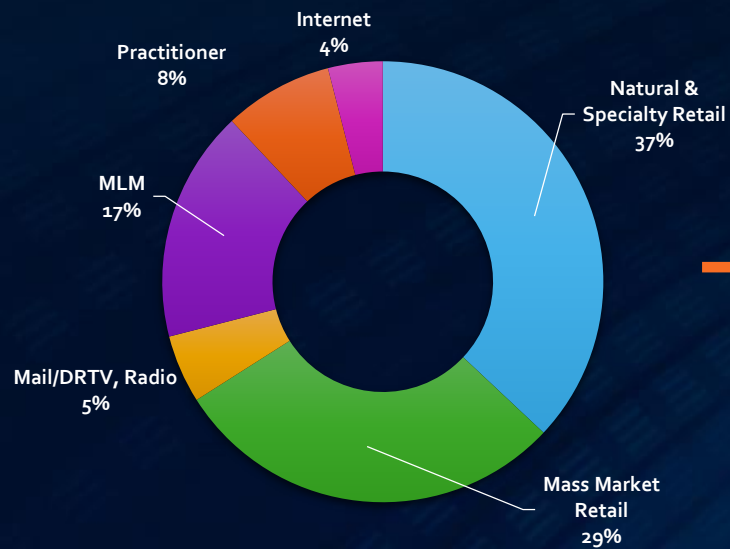
**Internet is showing highest growth** for several years in a row; Amazon continues to drive this and is starting to focus on its own private label

Market Data Update

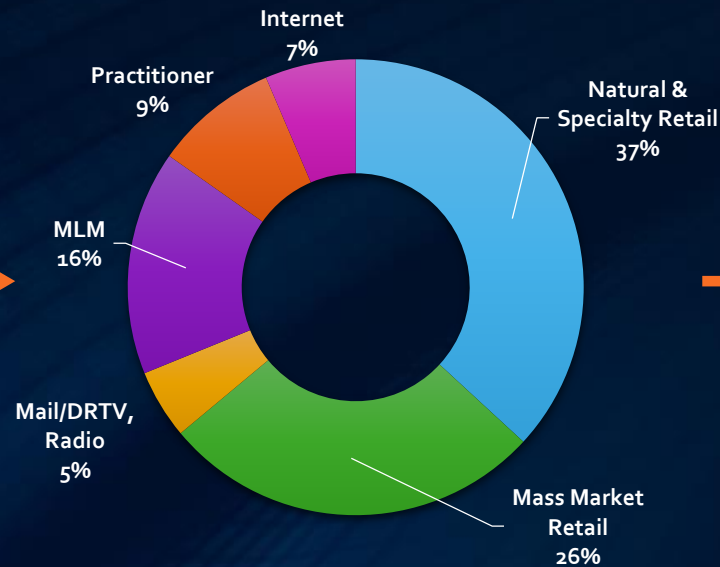
Source: Nutrition Business Journal

# US Supplement Sales Growth by Channel in 2016

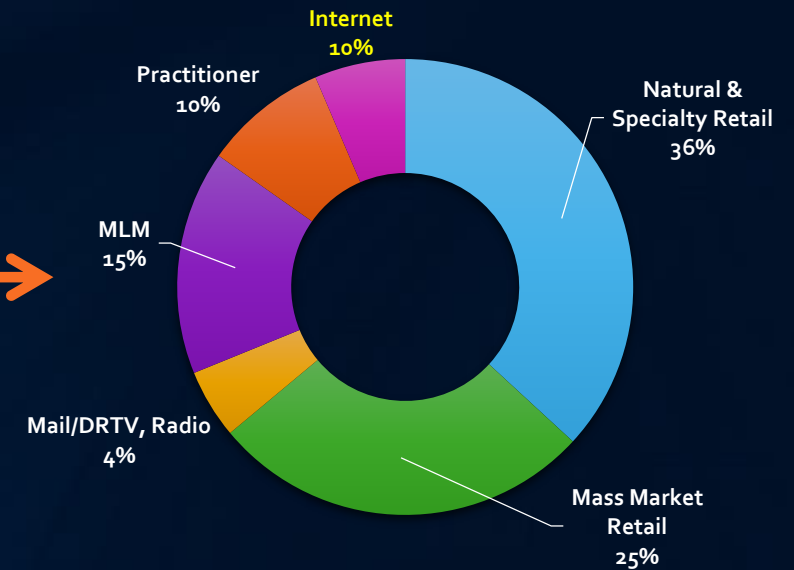
Sales in 2009



Sales in 2016



Sales in 2020<sup>e</sup>



Market Data Update

Source: Nutrition Business Journal

The Driver:  
Functional Medicine Works.



# Demands of the NEW Healthcare Consumer

- 1. Convenience** - patients are sick and tired of wasting time with inefficient and cumbersome customer service.
- 2. Transparency** - patients are sick and tired of blindly purchasing medical services only to be shell-shocked by a staggering bill.
- 3. Health** - patients are sick and tired of being sick and tired, no longer content with the delusion of health held tenuously together by a fistful of pills.

# Physician Reach

## Measures our Physician Database Growth by Year



NOTE: Physicians include MD, DO and ND primary degrees

Source: IFM

## The Challenge:

Physicians are not able to capture their fair share of the value they create.



# Battle for the Healthcare System

## Quantity vs Quality (Value)





# Cleveland Clinic



## **Personalized** Lifestyle Medicine Institute

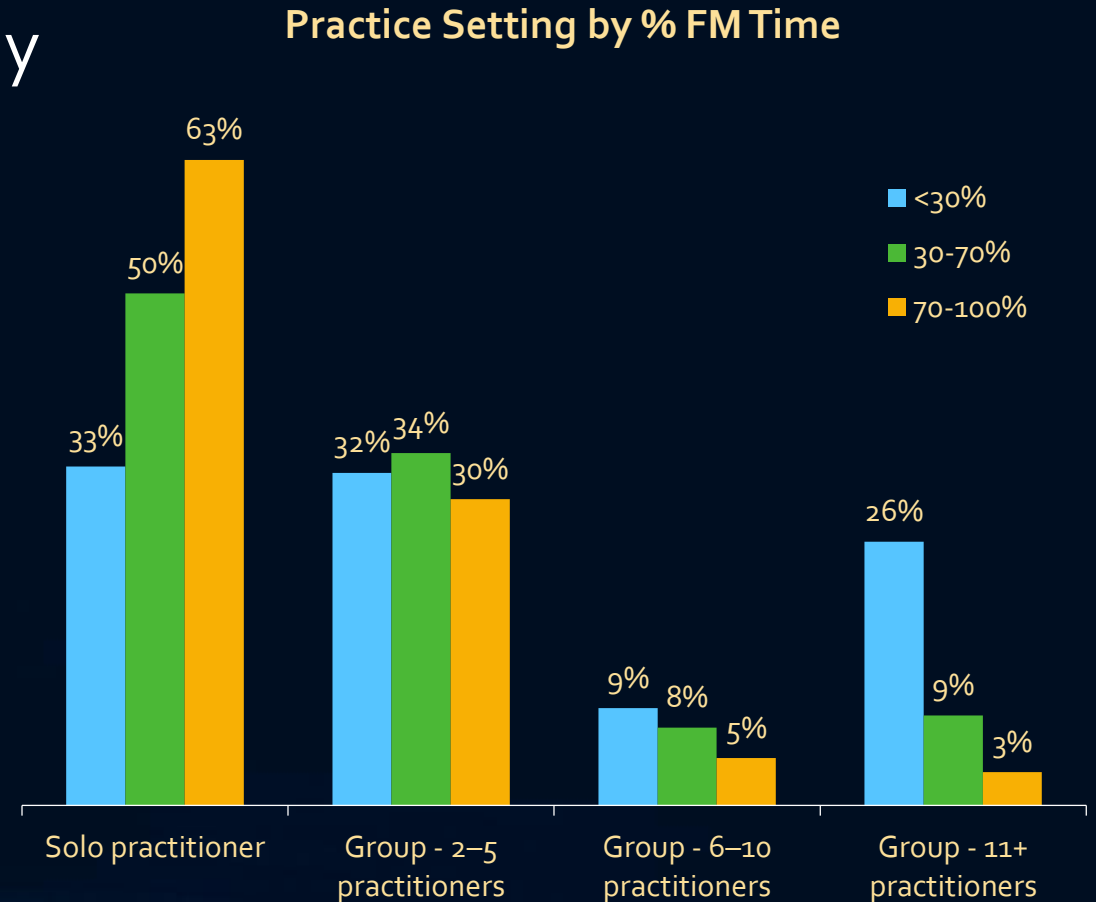
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# Patients Seen on Typical Workday (By % Time Practicing FM)

- Average Patients Seen per Day

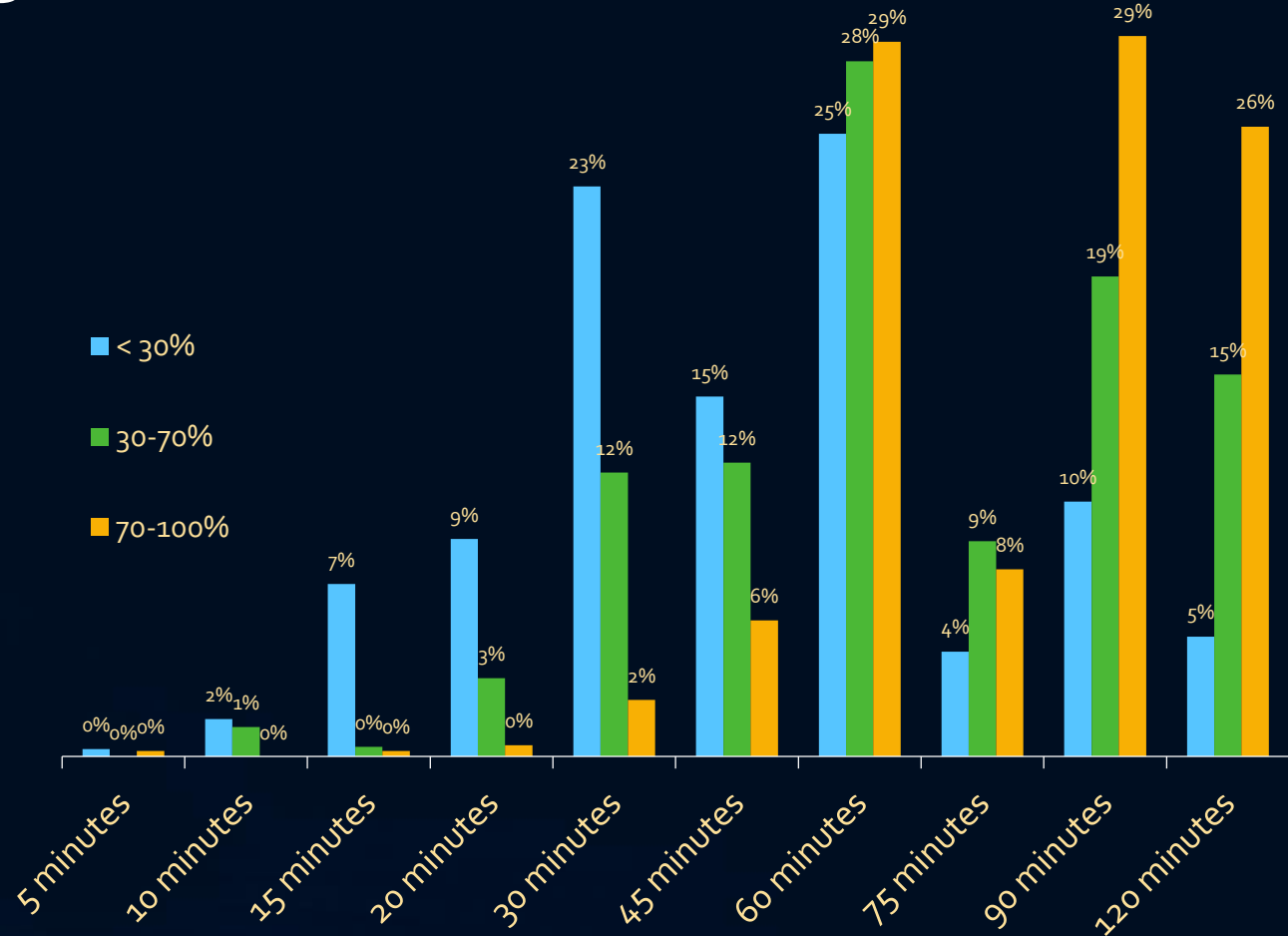
- <30%: 14.0
- 30-70%: 11.2
- >70%: 7.4

- Compares to 19.5 average according 2014 Survey of America's Physicians



# Time Allocated for New Patient Visit (By % Time Practicing FM)

- Average Time for New Patient Visit:
  - >70%: 83 min
- Average Time for Follow-up Visit:
  - >70%: 52 min
- Compare to an average visit time of 15 minutes (NCBI)

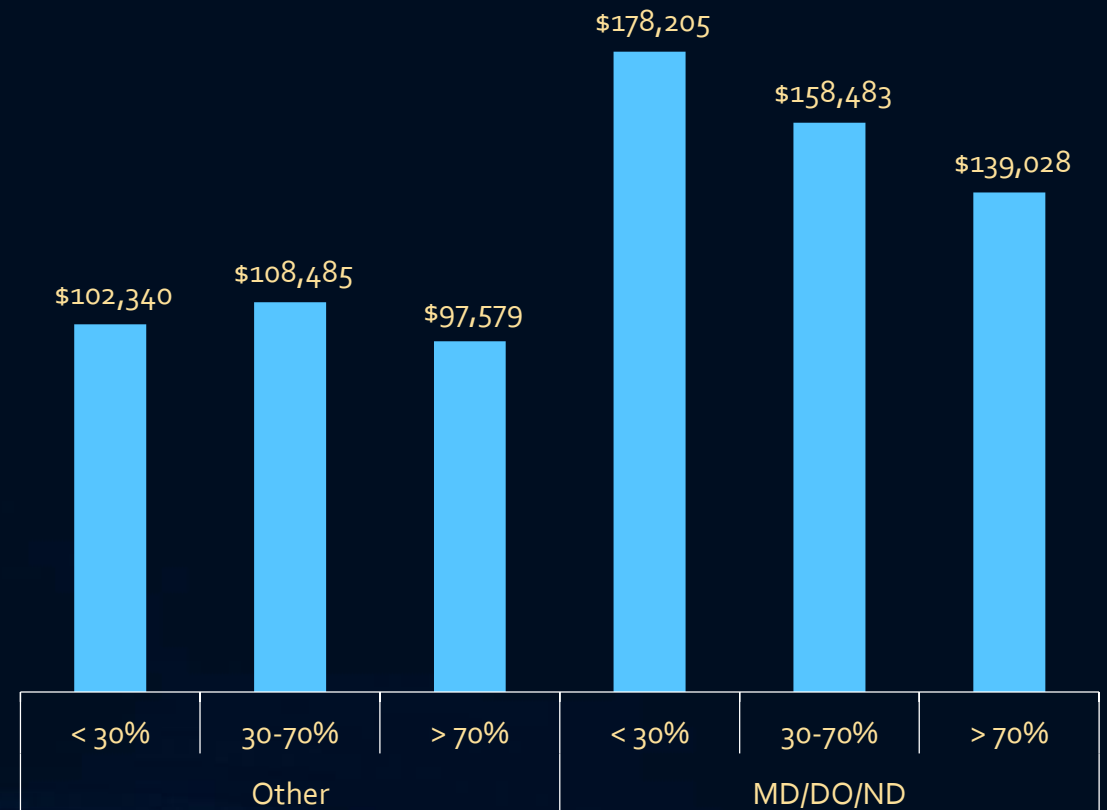




# Income by Professional Designation

- Average income: \$139k
  - 29% less than conventional peers
- Average hours worked: 60
  - 18% more than conventional peers
- Average hourly wage: \$54.75
  - 31% less than conventional peers

Income by Title and % FM Time





# Integrative Medicine Era

- Has the movement peaked?
  - Influential integrative clinics closing their doors
    - University of Arizona Integrative Health Center- development of various models of care. **Locked the doors July 2016**
    - Continuum Center (Mount Sinai – Beth Israel) – model for hospital based integrative centers. **Shut down 2016**
  - Leading research centers turning off the lights
    - Bravewell Collaborative – fostered creation of a network of clinics, research programs, and training curricula at major academic centers to re-humanize medical education and clinical practice. **Closed June 2015**
    - Samueli Institute - support academically rigorous research on health, well-being, and resilience. **Closed 2016**

The Opportunity:

7.4

Average annual income per daily patient:

\$18,787

88% MORE than conventional peers

Holding pricing and overhead constant,  
at 12 patients/day, FM practitioners earn  
\$225k.

15% MORE than conventional peers

How do we reach 12...

Without degrading outcomes?

Without further taxing the physician's time?





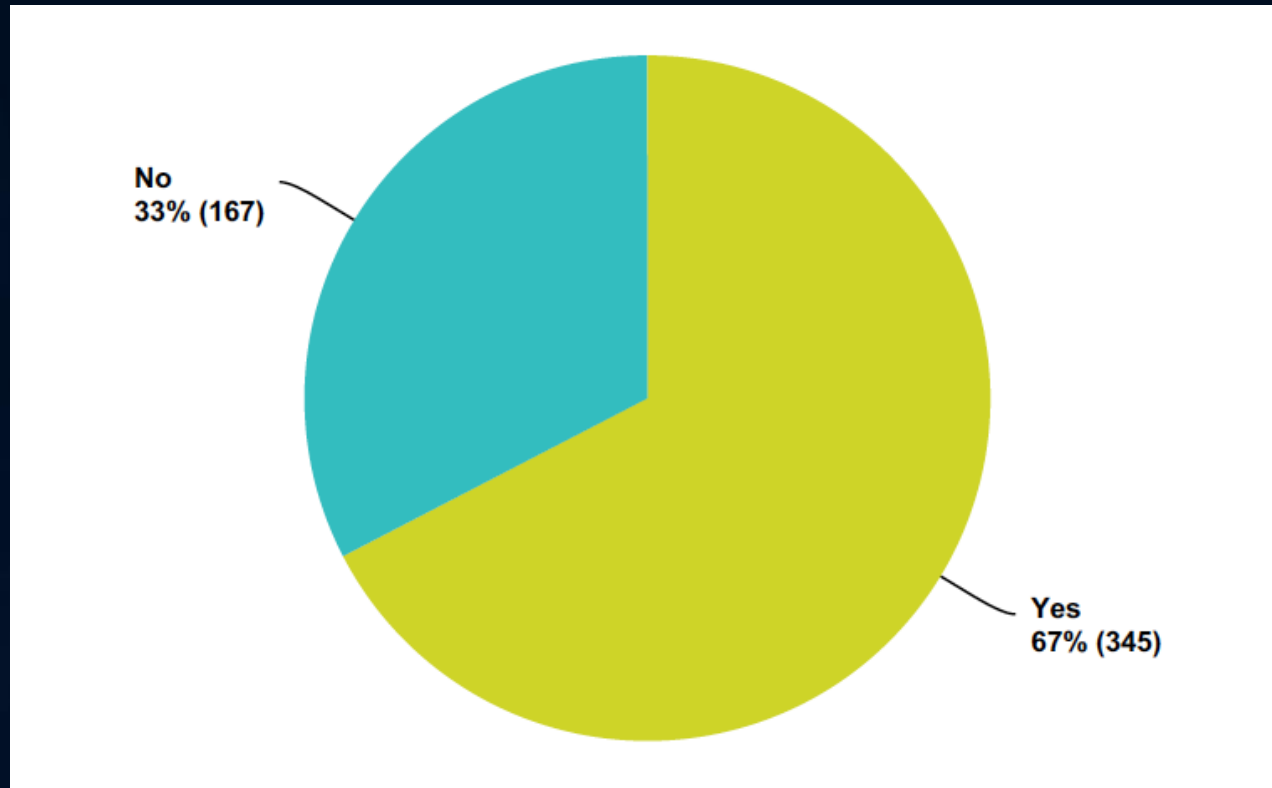
# Cleveland Clinic



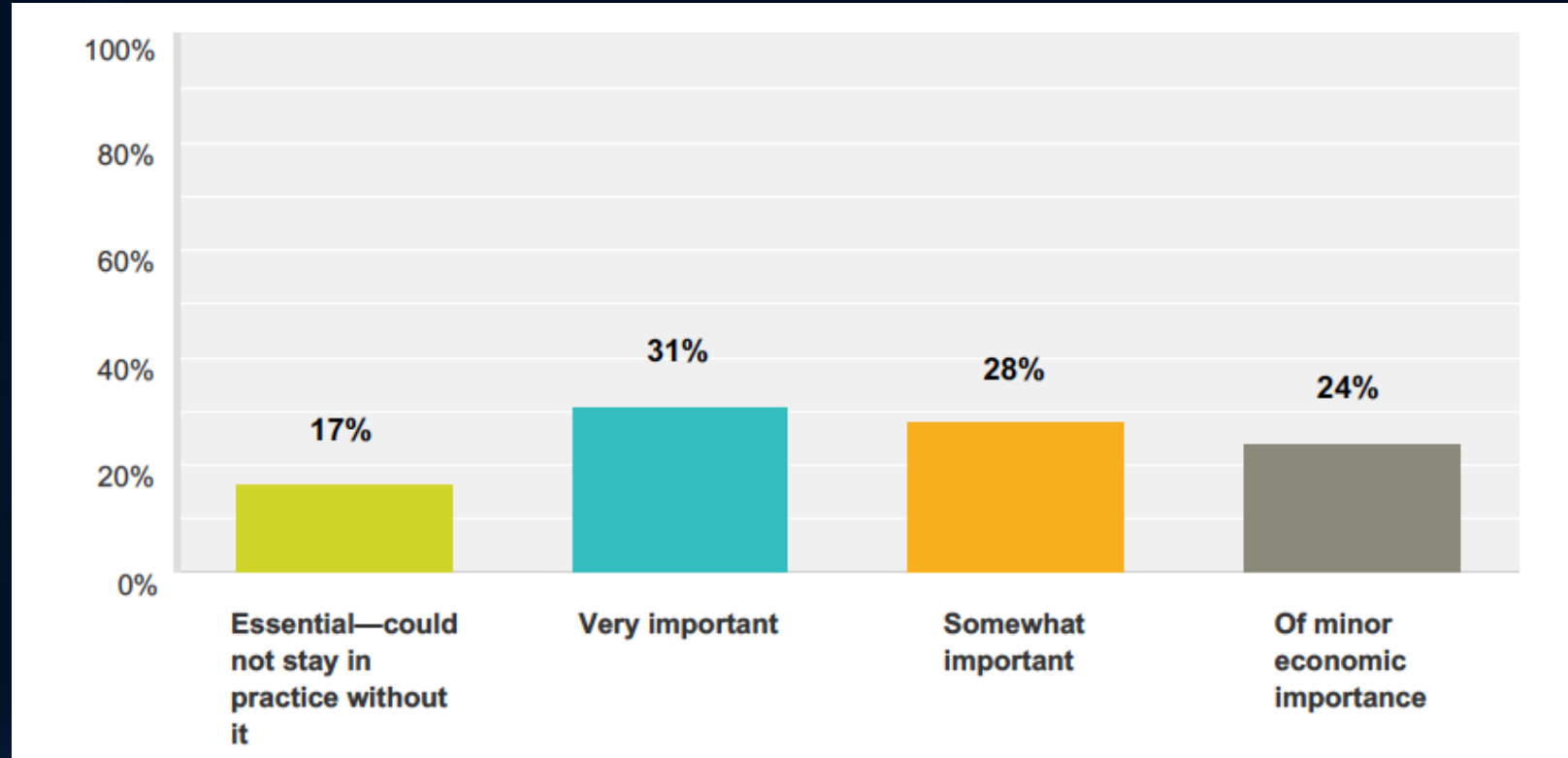
## **Personalized** Lifestyle Medicine Institute

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# Are you seeking a new revenue stream for your practice?



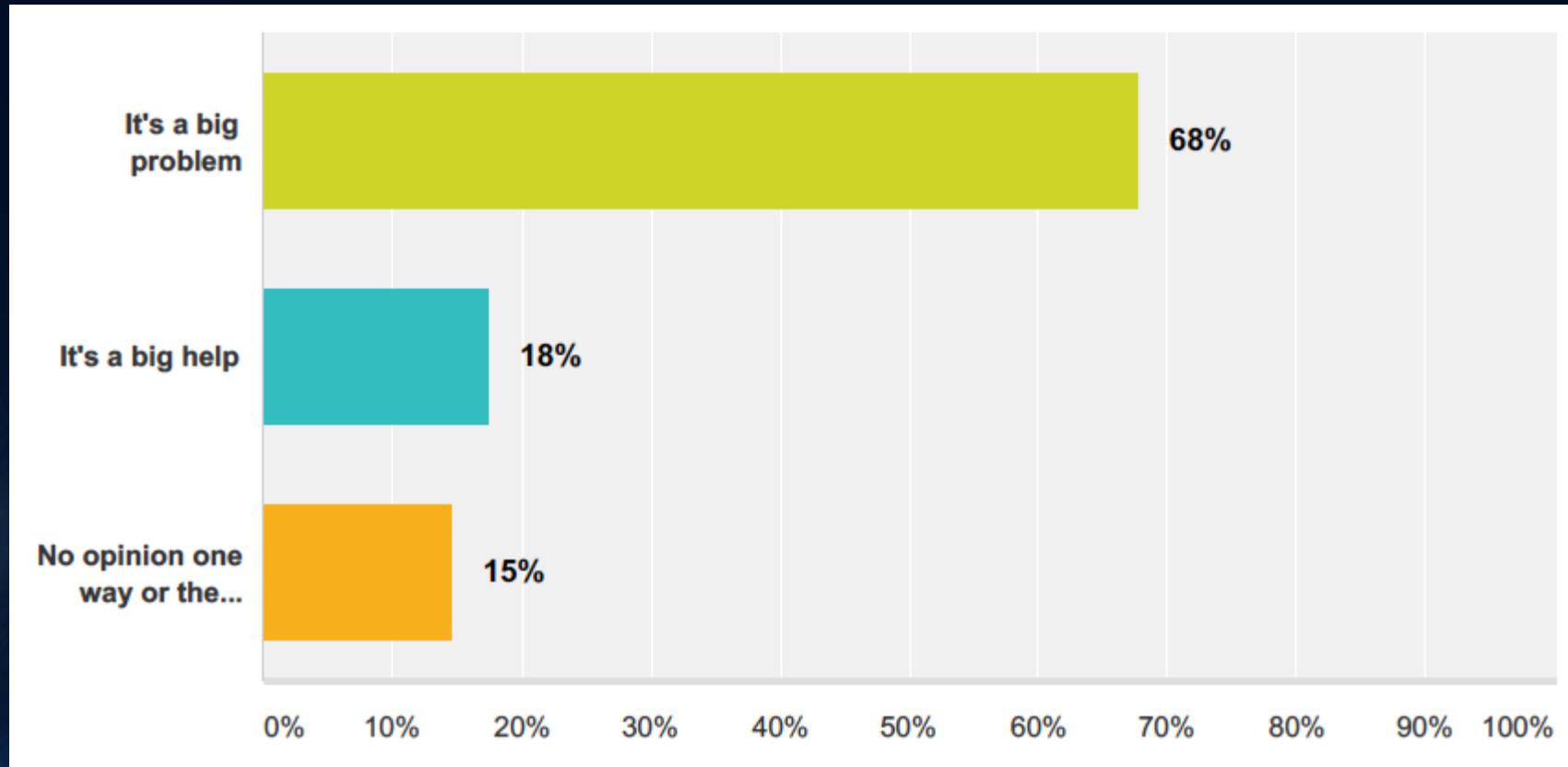
# How important is the revenue from dispensing to the overall economy of your practice?



# Industry Growth: Impact of Online Sales



# How do you feel about practitioner grade supplements being sold DTC via Amazon and other online retailers?





# Industry Growth: Impact of Online Sales

## Market Responses



# The Next Chapter

- Failure to Scale: The movement created significant change in the industry, but was the vision big enough?
  - Patient use of supplements is broadly accepted, but still few have access to affordable integrative medical services.
  - Practitioner membership in many integrative medicine organizations is flat or declining.
  - Integrative medicine remains a side business - 30% less income than traditional practices.
- Opportunity for the next generation
  - Realignment of the economic incentives in healthcare and influence of for-profit insurers.
  - Re-prioritization of integrative health with allopathic medicine
  - Integrative healthcare modalities created by a more diverse range of practitioners (currently now MD exclusive) and adopted by more conventional care systems (healthcare is being consolidated)

# Forging a New Path

- The Reality
  - Our Healthcare system is failing
  - The Affordable Care Act or any other Healthcare System that may replace the Act is simply not economically sustainable.
    - Disease paradigm versus an Aging paradigm
  - Healthcare practitioners feel economically squeezed.
  - Dietary supplements and other functional products potentially offer the means to help healthcare practitioners better manage their patients while providing a legitimate revenue stream.
    - Healthcare practitioners need access to truthful and non-misleading information

# Determining the Product Category

## “Intended Use”

- FDA determines the regulatory category of a product by examining that product’s “intended use.”
- “Intended Use” may be established by the following
  1. Claims in product labeling, in advertising, online or in other promotional materials
  2. Consumer perception, which may be established through the product’s reputation
  3. Ingredients or elements that have a well-known use
  4. Statements and representations made by a company’s sales force

# FTC Violations Related to Claims

## Misbranding

Misbranding in context of representation made to healthcare practitioners by a company includes not only the failure to follow FDA's labeling regulations, but also...

1. False or misleading information
2. Impermissible disease claims
  - a) Impermissible disease claims may also render the product adulterated



# Case Study

- *Amarin Pharma v. United States Food and Drug Administration et al.*, 15 cv-3588 (PEU) (S.D.N.Y. August 7, 2015)
  - Prescription drug company shared materials and study results with doctors the described off-label endpoints for their drug
  - Threatened misbranding action by FDA, claiming that the product is misbranded due to off-label promotion
  - Amarin filed for preliminary injunction, claiming First Amendment protected speech
  - Court ruled in favor of Amarin, finding that FDA was barred by the First Amendment from bringing a misbranding action over truthful non-misleading speech

# Case Study

- Implications of Amarin
  - What are the limitations of *Amarin*?
  - How does a case involving prescription drugs translate to dietary supplements and other FDA regulated products?
  - What would FDA's reaction be if companies begin to extensively rely on *Amarin*?

# Forging a New Path

- Paradigm Shift
  - Recognize the difference between aging and disease
  - Permit the communication of all truthful and non-misleading benefits of dietary supplements and other functional products to healthcare practitioners
  - Permit the use of Health Savings Accounts (HAS) for the purchase of dietary supplements

# Forging a New Path

- Legislation
  - Unique opportunity
    - Congress is controlled by Republicans
    - We have a healthcare crisis that requires a real solution
    - Whether you agree or disagree with the present administration, it is a disruptive administration that is bent on shaking Washington up.
    - New FDA Commissioner believes in out-of-the-box thinking

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