# No Fit-Test Respirator: Thoughts on Future Research in the Materials and Structures Areas

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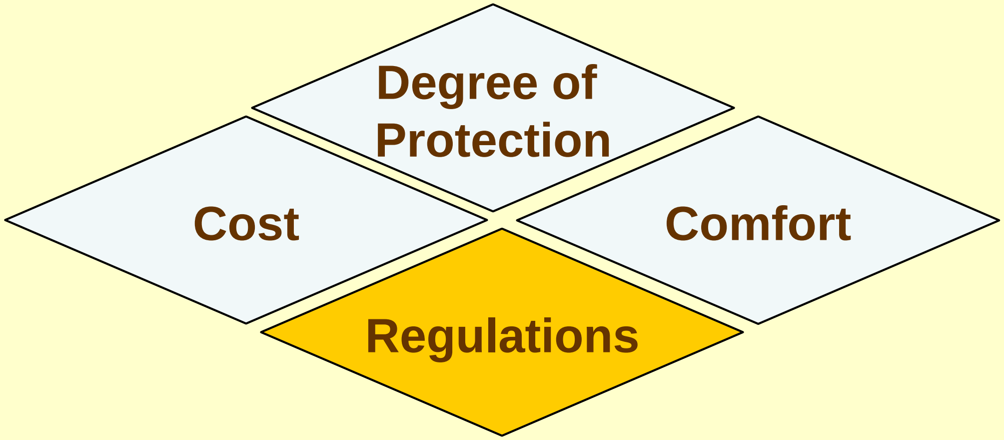
# Overview of Presentation

- The Design Drivers
- The Design Challenge
- The Design Toolkit
  - Materials
  - Structures
  - Manufacturing Technologies
- The Path Forward

Ron Schaffer: “Other Perspectives”

# The Design Drivers




Preparing for an Influenza Pandemic:
Personal Protective Equipment for Healthcare Workers
-- IOM Report, September 2007

<u>The Three Perspectives</u>

- End Users
  - Degree of Protection
  - Comfort
- Administrators/Providers
  - Cost
  - Life of Product
- Manufacturers
  - End Users
  - Administrators
  - Regulatory Agencies

- *Trade-Offs – The Balancing Act*

# The Design Challenge

- No Fit-Test
- Ensure Performance
  - Efficacy – Ensure Degree of Protection During Use
  - Avoid Leakage [Crutchfield et al., 1999]
    - Fundamental – Occurs When Donned
    - Transient – Occurs during Use
- Maintain or Reduce Total Cost of Ownership (TOC)
  - TOC = Respirator Cost + Fit-Testing Cost + …

# Framework for Design and Development

- The Key Design Drivers

Evidence-Based User Requirements Analysis

↓

Design Realization

↓

Field Use and Evaluation

↓

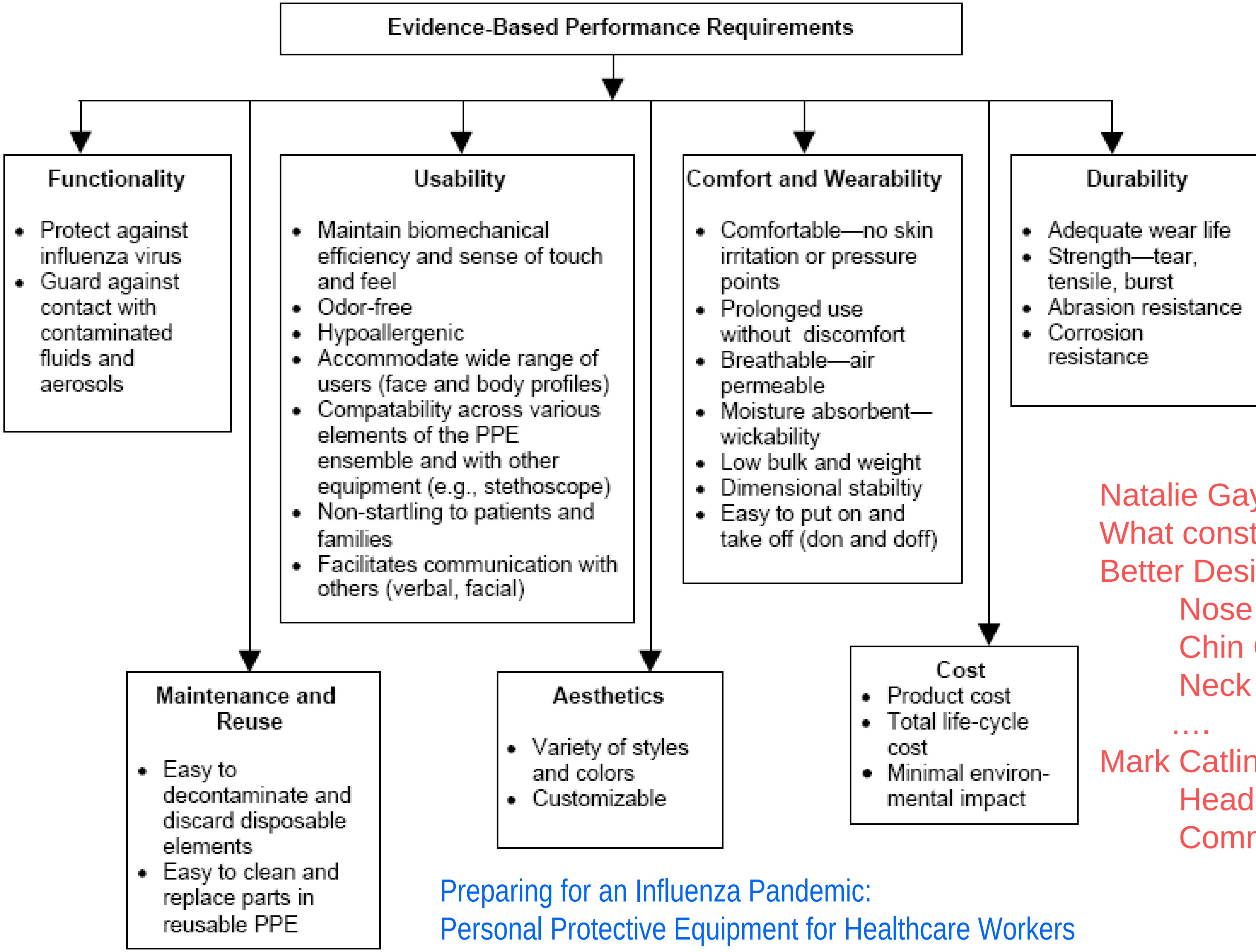
Market Introduction

Lisa Brosseau:

Product Development → User-Driven and Technology-Driven

Paradigm: A Careful Matching of User Needs and Technology Advancements

# A Structured Approach to Design




Natalie Gaydos, PPG
What constitutes a Good Fit?
Better Designed:
Nose Piece
Chin Cups
Neck Straps
….
Mark Catlin, SEIU
Headaches, Fatigue, …
Communication

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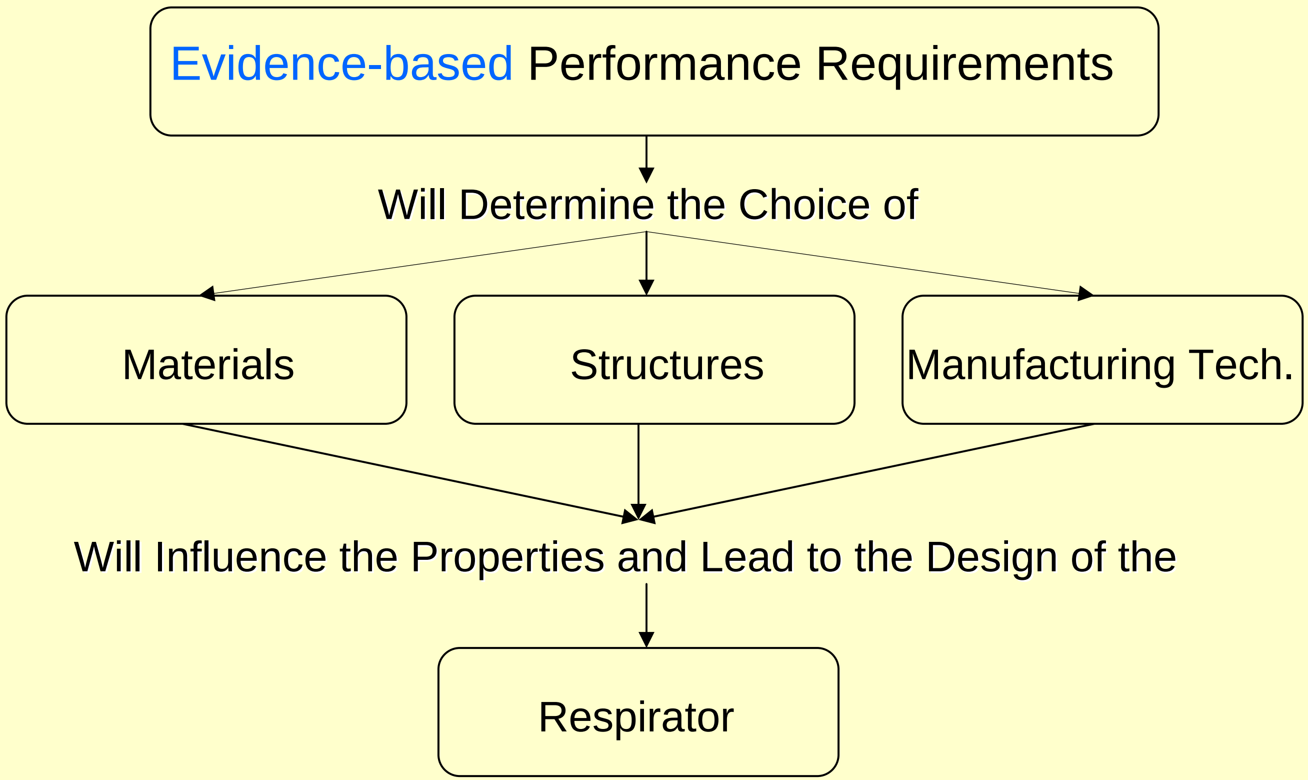
# Meeting the Challenge: Characteristics of the Face-Seal Interface

- Shape Conformance (Flexibility)
- Slip Resistance
- Shock Absorption
- Vibration Resistance
- Comfort
- Texture
- Hypo-Allergenic

Easy to Put On, Stay in Place → Prevent Leakage

# The Design Toolkit



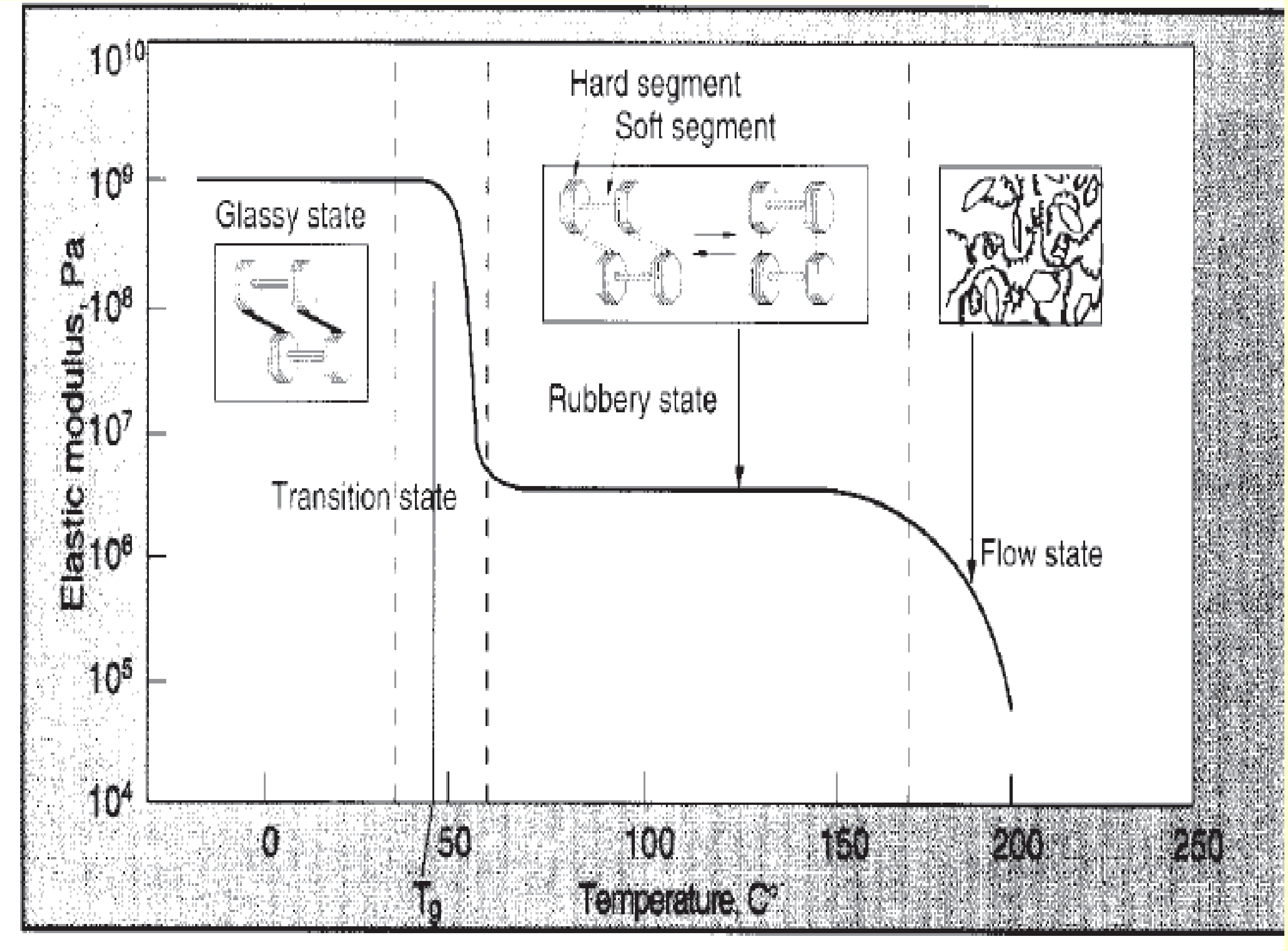

Driver: *No "Fit-Test"*

Efficacy, Comfort, Wearability, …

# The New Materials

- Shape-Memory Polymers
  - Remember and Recover Shape Based on External Stimuli (e.g., Temperature)
- Gels
  - Can Change *State* Depending on Stimuli (e.g., Temperature)

# Polymers: Temperature-Modulus Relationship



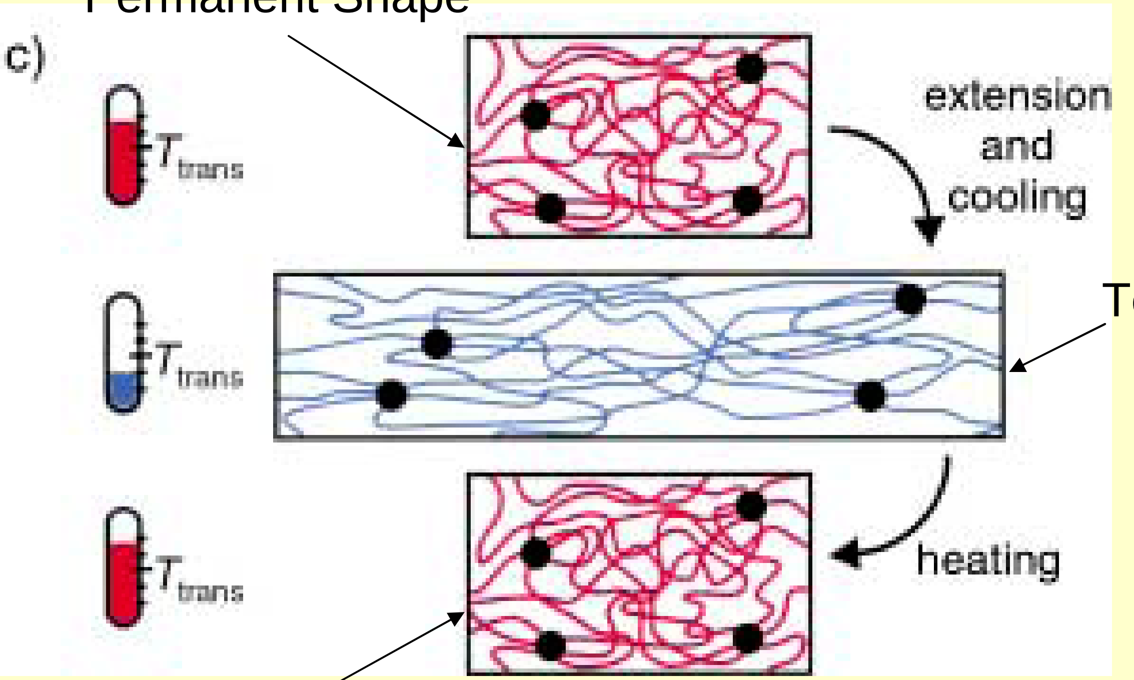

**Source:** Shunichi Hayashi; Satoru Kondo; Pragna Kapadia; Eiji Ushioda, "*Room-temperature-functional shape-memory polymers", Plastics Engineering;* Feb 1995; 51, 2; 29-31.

# Behavior of Shape-Memory Polymers

- Create a Temporary Compacted State by Heating Polymer above its Glass Transition Temperature ($T_g$) to a Soft Rubbery State.
- Deform Polymer to Desired Temporary Shape and Cool under Constraint to Set the Material in this Temporary State
- To Recover Original Shape: Reheat Polymer to $T_g$
- Polymer Recovers Original Shape
- Reasons for Behavior:
  - Restriction of micro-Brownian Movement Below $T_g$
  - Shape Recovery Due to Entropic and Internal Energy States
- Thermoset Polymers: Good Example

# How Shape-Memory Polymers Work?

Permanent Shape

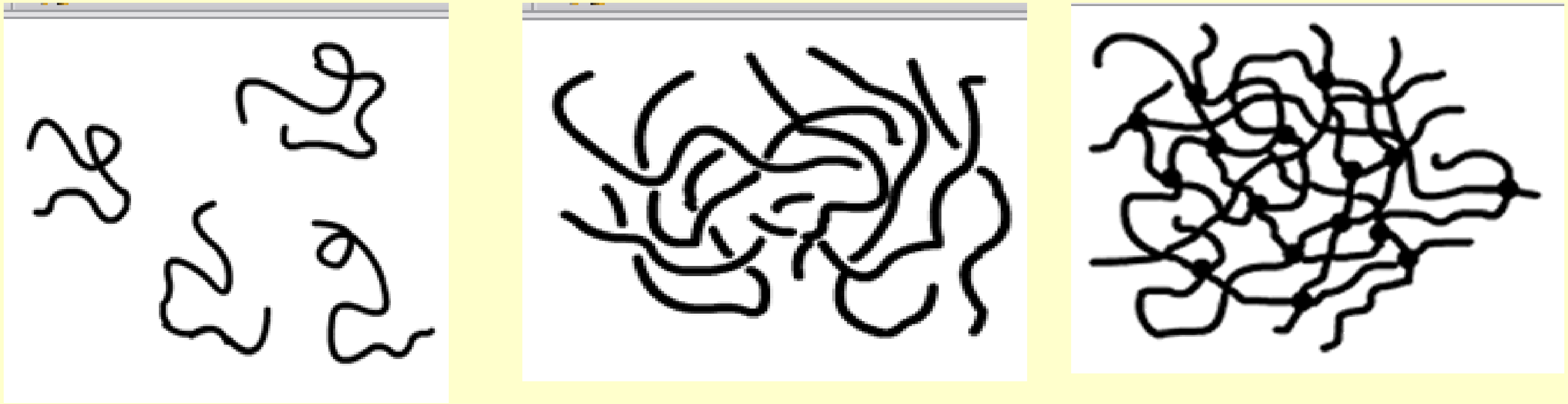



Recovery of Permanent Shape

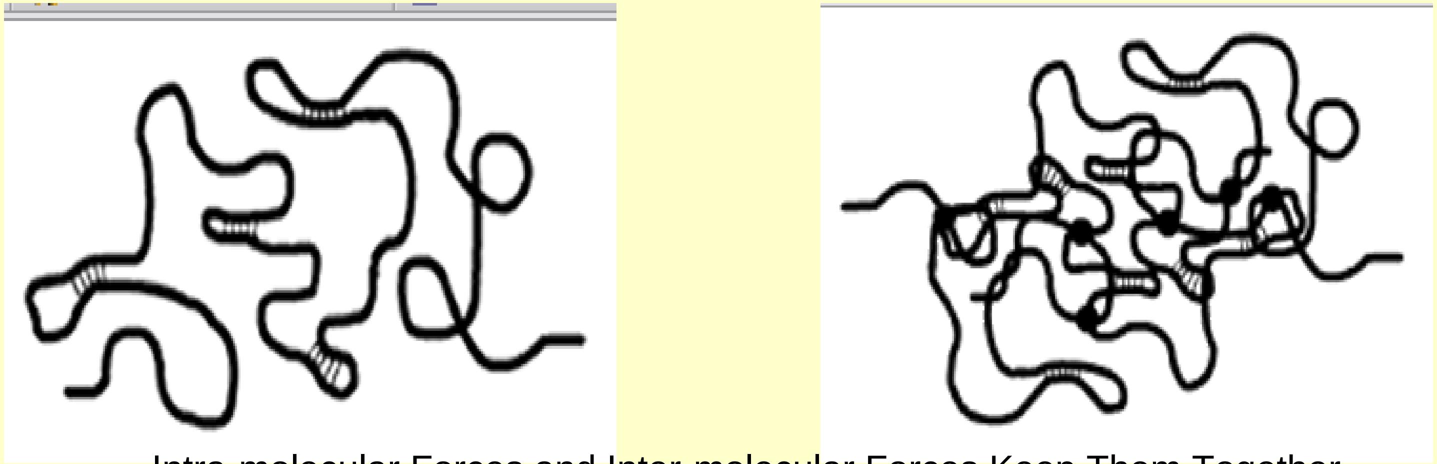
By Heating Permanent above Tg and ***deforming***, the Temporary Shape is Formed.
By Heating the Temporary Shape above Tg, the Permanent Shape is Recovered.

Source of Figure: Shape-Memory Polymers by Lendlein, A., and Kelch, S., *Angew. Chem. Int. Ed*. 2002, 41, 2034-2057.

# Polymer Gels



Solvent Concentration Decreases → Molecules Coalesce → Form Gel



Intra-molecular Forces and Inter-molecular Forces Keep Them Together

http://www.pslc.ws/macrog//level3.htm

# How Gels Work?

- The Gel Molecule
  - Acts as a Dilute Solution
  - Coil Segments Move Freely → Micro-Brownian Motion
  - When Deformation is Applied → They React (Squishy) → Are Elastic
  - Properties Change with Degree of “Cross-Linking”
  - Greater The Degree of X-Linking → Harder the Gel → Rigid
- Everyday Examples
  - Jello (Gelatin)
  - Baby Diapers: Polyacrylic Acid inside Diaper Soaks Up Water Keeping Surface “Dry”

# Thermoplastic Elastomers

- Thermoplastic Elastomers (TPE)
  - Flexible Materials that Can be Stretched Repeatedly at Room Temperature and Returned to Original Length When Released (Deformation Removed)
  - Look, Feel and Elasticity of Themoset Rubbers + Processing Capabilities of Plastics
  - Easy for Extrusion, Injection Molding

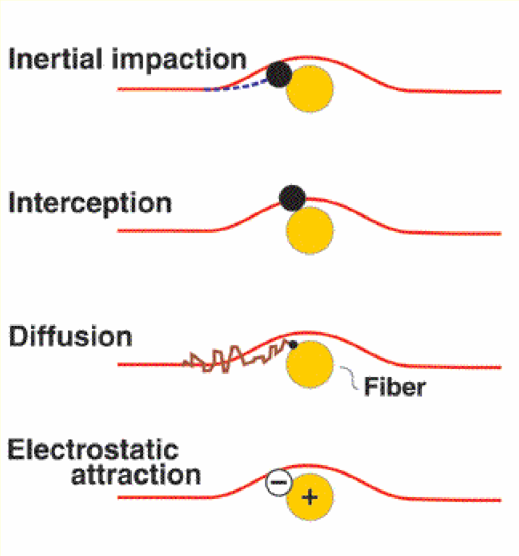
- Commercially Available

| Property | S+ gel | M gel | T gel |
|---|---|---|---|
| Hardness Range | Babies' skin to hard rubber ball | Gummy bear to soft pen grip | Pencil eraser head to a rigid plastic case |
| Exudes Oils | Minimal | Yes | No |
| Cushions & Protects | Yes | Yes | Yes |
| Medical Grades Available | Yes | Yes | No |
| Industrial Grades Available | Yes | No | Yes |
| Adheres to Fabrics & Substrates | Yes | Yes | No |
| Durable | Yes | No | Yes |
| Washable & Reusable | Yes | Yes | Yes |
| Non-Allergenic | Yes | Yes | Optional |
| Relative Material Cost | High | Moderate | Economical |
| Tensile Strength | Excellent | Good | Excellent |
| Ultimate Elongation | Good | Excellent | Excellent |
| Tear Strength | Excellent | Excellent | Excellent |
| Compression Set | Better in Low Durometers | Better in Higher Durometers | Better in Higher Durometers |

http://www.gelsmart.net/index.php?option=com_content&task=view&id=33&Itemid=74

# Structures and Manufacturing Technologies

- Traditional Respirators/Masks
  - Nonwovens
  - Charged Polypropylene Filters



Mechanisms for Trapping Particulates


3M N95 Healthcare Particulate Respirator & Surgical Mask

# Alternative Approaches: Back to the Roots

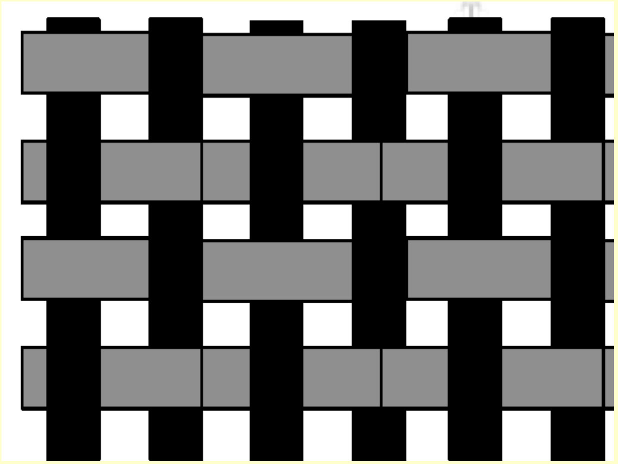
- Other Manufacturing Technologies
  - Weaving / Knitting + Nonwovens

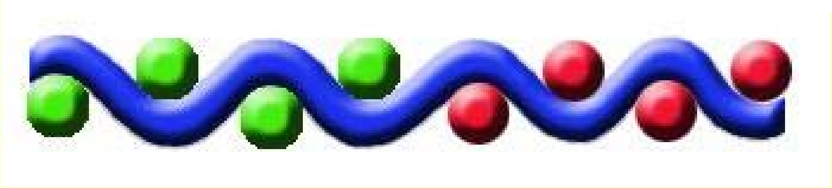
- Yarn Properties
  - Fiber Type
  - Fiber Cross-Sectional Shape
  - Linear Density
  - Twist Level
  - ….

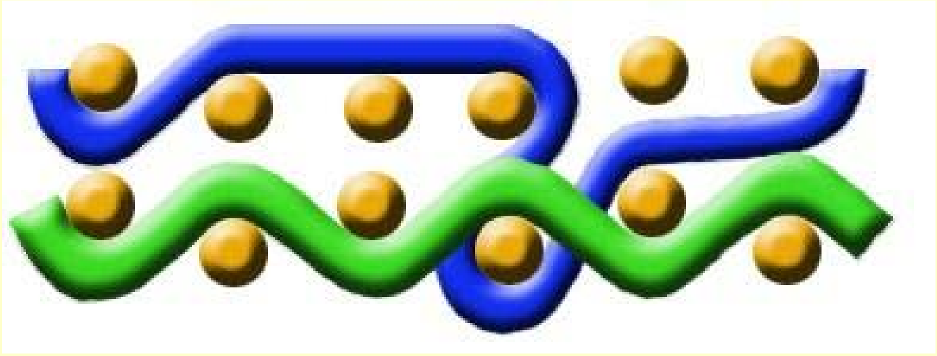
- Fabric Properties
  - Threads Densities
  - Structure
  - …

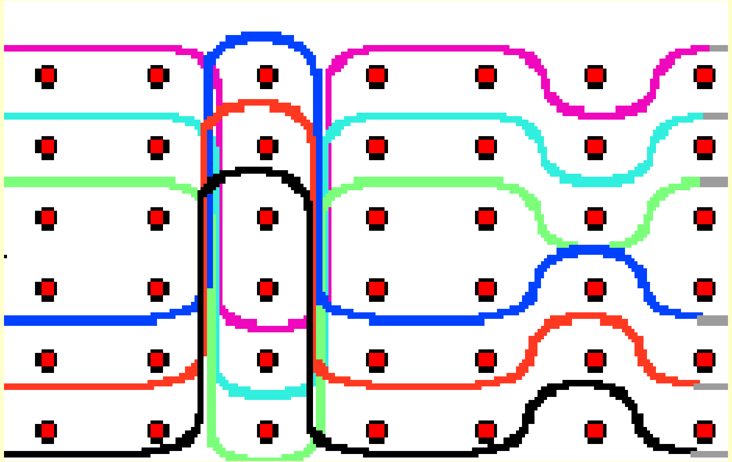
# Structural Variations

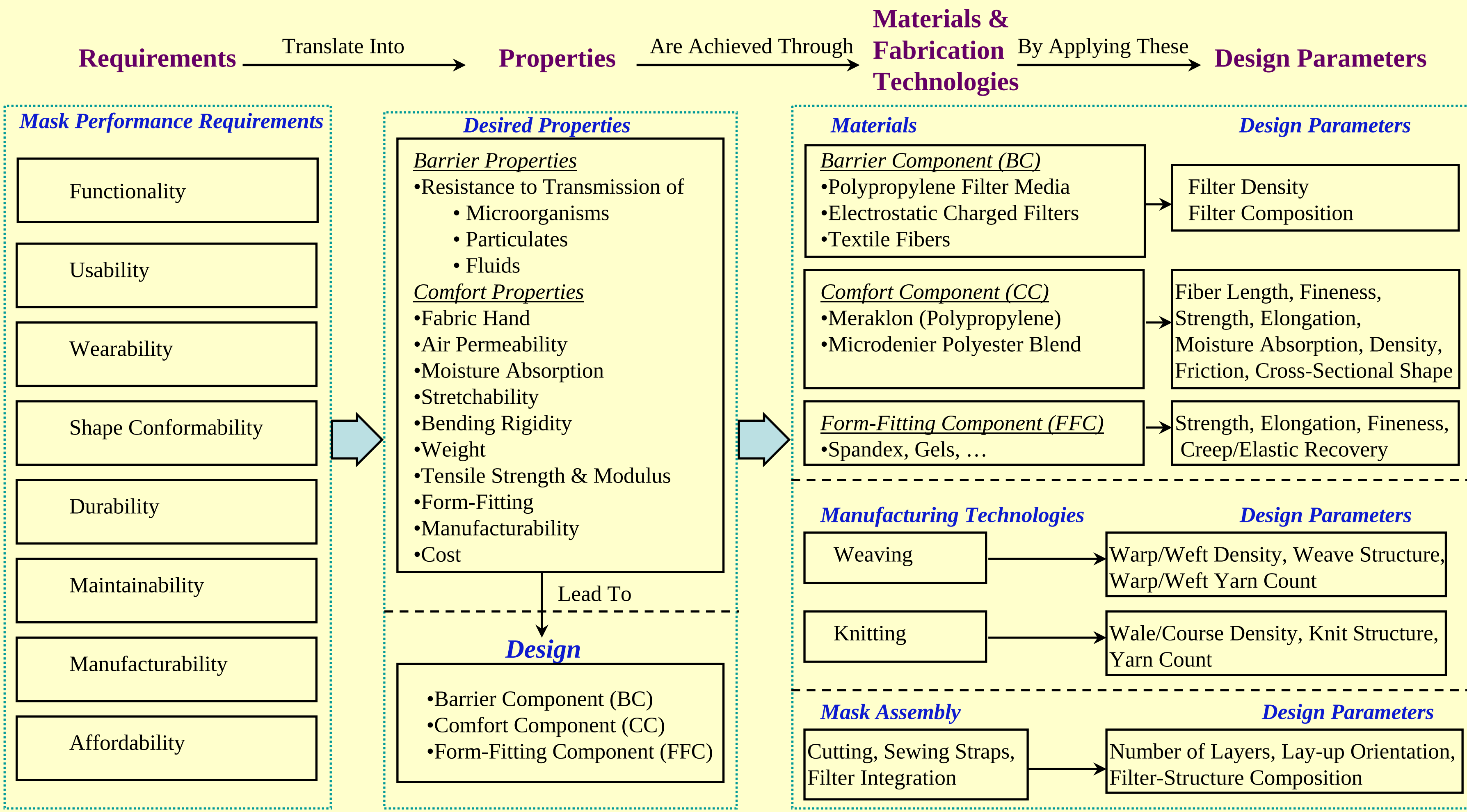











A Framework for Design and Development

# The Path Forward

- Research Initiative
- Investigate Alternative Approaches
  - Systems Approach
    - Materials
    - Structures
    - Manufacturing Technologies
  - Design, Development and Testing
- Next Generation Healthcare Respirator-Mask

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