Ramifications of Supply Chain Changes
Our mission and purpose

Our mission: To translate scientific discovery and technology advances into societal benefits

- Nonprofit, charitable trust formed in 1925
- Profits reinvested in science & technology and in charitable causes, making the world better for generations to come
- Knowledge, talents and resources applied to help our customers achieve their most important goals
Supply chain changes are scary.
Barex is going away…

• Acquired by INEOS in 2005 from BP Chemicals
• October 2014 – Announced closure of the sole production facility in 1Q 2015
• Production continued into 2016
• July 2016 – Preliminary agreement to sell IP and assets to MSM Poly, LLC
• September 2016 – Terminated discussions and plans to close production and dismantle facility
Barex is a great material

- Acrylonitrile-methyl acrylate co-polymer developed in 1960s – commercialized in 1975
- Excellent oxygen barrier and heat sealing attributes
- Versatility in processing:
  - Converted to bottles, blown film, sheet and molded parts
  - Extrusion, injection molding and calendaring processes
- Packaging:
  - Lighter – comparable stiffness with thinner film
  - Impact resistance
  - Extend shelf-life of food
Barex has many applications...

• Packaging for pharmaceutical, medical and food products.
• Chemical resistance and superior barrier properties
  ▪ Low ingress of water and oxygen
  ▪ Low absorption and egress of APIs (e.g., nicotine)

• FDA:
  ▪ Direct food contact
  ▪ Non-carbonated, aseptic-filled beverages

• EU:
  ▪ Direct food contact
  ▪ Beverage use
  ▪ Liquor packaging (up to 50% alcohol)
Growth was trending in pharmaceutical packaging

• Focused on transdermal drug delivery packaging
  ▪ >12% CAGR 2014-2018

• Food packaging use in decline
  ▪ Oscar Mayer bologna switch in 2010

• Smaller market, but perhaps a more critical need
Industry has responded

• Urgent replacement need – timeline of months rather than years to accomplish
• Wants diversified options to avoid another niche chemical/material solution

Approaches:
- Equivalent material production
- Evaluations of existing materials
- Incrementally modified products
Equivalent Material

MSM Poly, LLC

• Formed in direct response to a core group of pharma packaging companies

• New drop-in replacement Barex-like material
  ▪ Acrylonitrile methyl acrylate copolymer (AMAC) latex resin
  ▪ Commercial production of Anobex anticipated in early 2017
  ▪ Few million pounds per year vs. tens of millions of pounds per year
  ▪ Building redundancy into manufacturing process with capabilities at multiple sites
Equivalent Material

Amcor

- Secured 3 year supply for its customers to bridge gap to an alternative
- Developing “alternative film which has the same inert properties as Barex, improved extractables and sealing properties”
- Removing the dependency on a single manufacturing site
- Recognizes critical nature of applications and complexity of any requalification process
Evaluations of Existing Materials

• Polyethylene terephthalate (PET), glycol-modified PET (PET-G), ethylene vinyl alcohol copolymer (EVOH) and polyolefins

• Cyclo-olefinic copolymer (COC)
  ▪ Ethylene-norbornene copolymer
  ▪ Moisture barrier and low absorption of some AIs (e.g., wintergreen)
  ▪ Medical and food contact compliant grades
Incrementally Modified Products

Rollprint Packaging Products, Inc.

- Exponent2: ClearFoil technology and a coextruded non-crystalline polyester sealant
- Peelable Exponent: easy-to-open sealant

Bemis Healthcare Packaging

- PerfecPharm P616 (CXB Sealant) and P619 (PET Sealant)

Tekni-Films

- “Polyethylene, polypropylene and Aclar PCTFE inner and outer layers, coupled with either EVOH copolymer and/or COC for enhanced barrier properties.”
Failures Occur Because of the Complex Interplay Between Structure-Process-Environment on Properties

Medical Device Material Failure Assessment
Do we have the right requirements and specifications?

- Broad chemical resistance
- Low water vapor and low oxygen permeability
- Transparency
- Heat sealing
- Regulatory approvals
How do we identify and mitigate risks?

• Needs dictated by the application – e.g., food vs. medical

• Prioritize product requirements
  ▪ Value trades
  ▪ What else could/should change?

• Design appropriate test plan
  ▪ Anticipated interaction(s)
    – APIs, material-material, environmental, processing, etc.
  ▪ Specific to the process and use
  ▪ Relevant timeframe
Is there an opportunity to make a better product?

• Optimized films for different APIs
• Multi-layer vs. single component systems
  ▪ Complexity and control vs. simplicity
• Consideration of new process options
• Thinner, lighter weight structures
• Introduce new consumer oriented features
  ▪ “easy-to-open”, seal integrity indicators, etc.
Wrap Up

- Market for Barex properties has/will continue to change
- Alternatives are available
- Effectiveness of options depends on the use
- Relevant performance testing is necessary
- Are we in a better position?
Thank You!

Jeff Cafmeyer
cafmeyerj@battelle.org
614-424-3048