3D Printing
From Hype to Reality and Insurance Implications

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Introduction and Background

Why Discuss 3D Printing?

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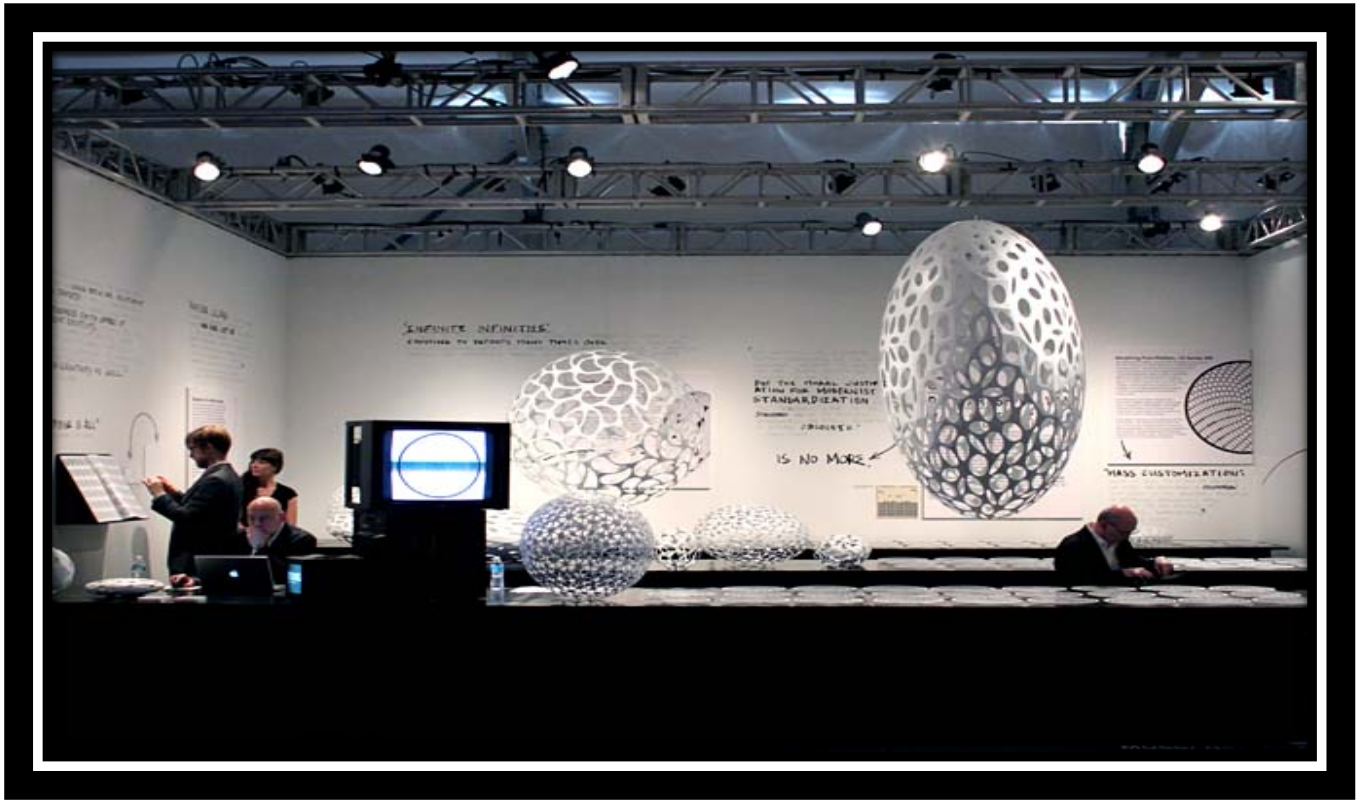
New emerging risk insights

Change remains the only constant in our highly interconnected world. Risks are emerging everywhere, with ripple effects across industries. Foresight information is the key to enabling fast, high-quality decision-making.

Welcome to the New Age

One of many questions that will affect insurers:

- How will the capabilities of 3D printing, especially mass customization, alter liability and traditional insurance coverage models?



Today's program

- Background on what is 3D printing and why it is so exciting
- Which industries are most affected?
- How 3D printing may reshape some product liability standards
- Claims scenarios
- Underwriting and risk management considerations

Why the interest in 3D printing?

3D printing is poised to revolutionize the manufacturing world.

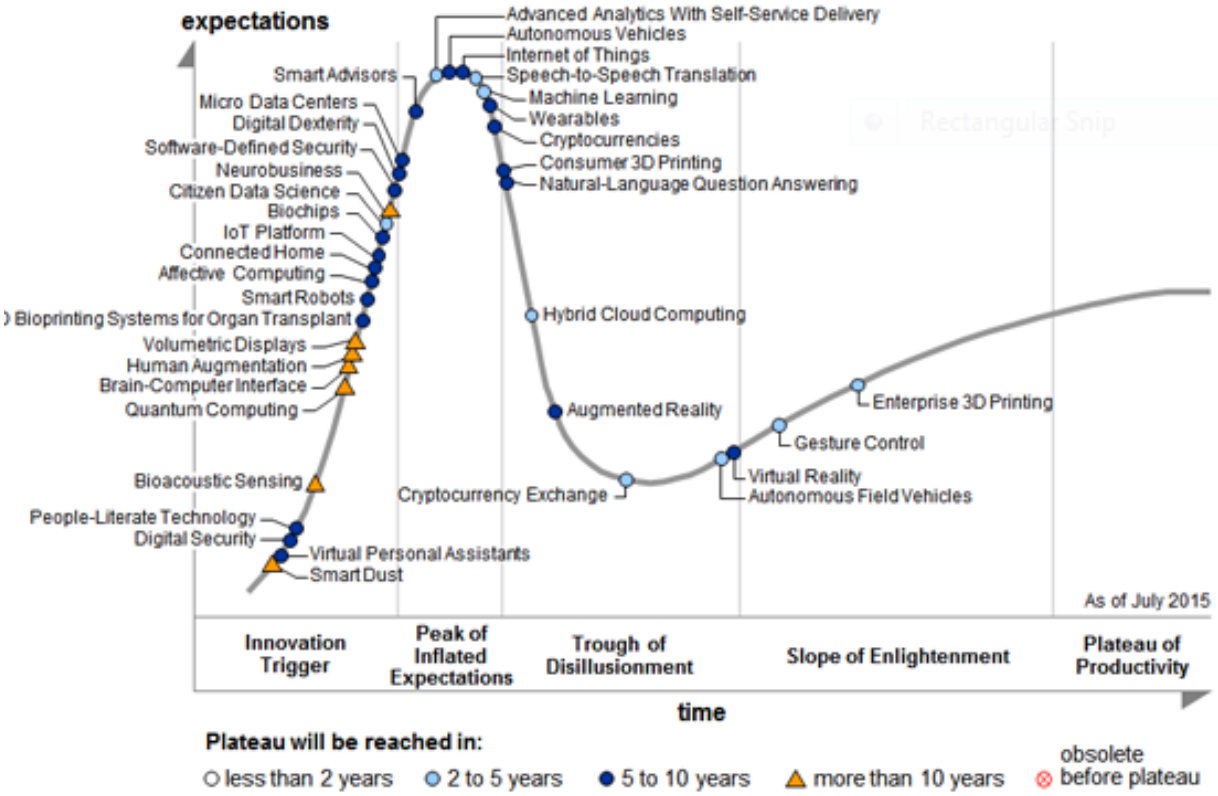
"Leaders must consider the strategic implications as whole commercial ecosystems begin to form around the realities of 3D printing." The 3-D Printing Revolution, Harvard Business Review, May 2015.

"Industrial 3-D printing is at a tipping point, about to go mainstream in a big way." The 3-D Printing Revolution, Harvard Business Review, May 2015.

The industry consensus is that 3D printing has evolved beyond the hype, prototype and novelty stage and must be recognized as a mainstream technology.

3D printing presents novel liability issues that need underwriting consideration, risk management attention and coverage evaluation.

Hype creates expectations .... which are sometimes achieved



Source: Gartner's 2015 Hype Cycle for Emerging Technologies

3D printing – how big is it?

- Accurate figures and projections are challenging but based on 2015 figures ....
  - $5.2B for products and services (does not include R&D or revenues from manufactured products)
  - over 12,000 industrial systems sold (price > $5000)
- Some recent acquisitions > $1B
- One projection is for $30B by 2022

3D printing – what is it?

- 3D printing is a process of making a three dimensional solid object of virtually any shape from a digital model.
- This is an *additive process.* That is, successive layers of material are laid down in different shapes.
- This is distinct from traditional machining techniques that generally rely on the removal of material by methods such as cutting or drilling (*subtractive* processes).
- Common materials used are plastics, synthetic resin, plaster powder, glass powder, metal powder, thermoplastics, ceramics, food (oils and powders) and cement.
- How about biomaterials such as living tissue? >> the expanded use of new materials is key to the success and growth of 3D printing

3D printing is also known as ....

- Additive manufacturing
- Additive fabrication
- Additive processes
- Additive techniques
- Additive layer manufacturing
- Layer manufacturing
- Freeform fabrication

We need to be able to recognize it when we see it

Why is it so exciting?

1. Much shorter development times for new products
   - The ability to develop multiple prototypes that can be used for market research, customer demonstration and testing. Which ones will end up as real products?
   - Reduced tooling costs compared to conventional manufacturing techniques.
2. More simplified production operations (for example, less movement of unfinished goods and reduced need for overseas manufacturing)
3. Reduced waste
4. From 2000 – 2010, the US lost 5.7mm manufacturing jobs. Recently, this trend has begun to reverse. 3D printing is one technology that hopes to revitalize US manufacturing.

Challenges

- Size and scale
  - print large objects on small machines that are then ‘unfolded’
- Speed
- Software development
  - bioprinting
  - multi-materials
  - printed electronics
- Printing materials
  - print with the same materials as we do now, just in a different way, or
  - a whole new episode in materials science >> new materials and properties capable of new performance and behavior

Only 3D printing?

- The phrase “3D printing” does not cover the magnitude of the technological evolution happening today. 3D printing is a component of a larger shift to digital fabrication (Dfab).
- 4D printing
  - the 4th dimension is time
  - the code of the printed object determines its shape and dictates how it can be stimulated to change when confronted with a change in environment, such as water, movement or temperature:
    - a pipe that responds to temperature or pressure to expand or contract
    - bricks that can respond to changes in stress
    - a medical implant device that can change shape as the body grows or moves

Implications for business and society

- Additive manufacturing = mass customization
- Is it really ‘anything you want, anywhere you want it’ ?
- Some big questions:
  - assembly plants: are they still needed?
  - how does the very nature of the manufacturing sector change?
  - what does that mean for the retail sector?
  - what does that mean for the logistics sector?

Radical adjustment to current delivery models

Inventory

- 3D printing may dramatically reduce inventory needs.

Geography

- Remote location supply availability: Why order and wait for a delivery? Just print what you need when you need it.

Mass Production

- Some industries rely on mass production; will 3D printing introduce greater efficiency, less waste? less seasonal or cyclical overstock?

These needs are all different, yet 3D printing offers opportunities for each of them.

Example: 3D printing manufacturing and delivery models

- Manufacture can occur in home (no external manufacture, inventory or delivery)
- Manufacture can occur immediately on site by order (no inventory)
- Manufacture can occur AT DELIVERY.

Amazon Files Patent for Mobile 3D Printing Delivery Trucks

BY BRIAN KRASSENSTEIN · FEBRUARY 25, 2015

Industries Impacted by 3D Printing

Applications in aerospace & automotive

- Early adopters, especially for rapid prototyping
- Because prototypes are produced faster, it is possible to shorten production cycles tremendously and allow engineers to experiment with different features of the final product. This often results in lower costs.
- Used now to produce final parts
- Future applications will depend strongly on material science research and the production of innovative parts based on new designs and embedded functionalities.

Can a car actually be made with 3D printing?

- about 75% of it is 3D printed (goal is 90%), combination of plastic and carbon fiber
- working to get crash test certified
- customize aesthetic features on a standard platform
- 50 parts vs. 30,000 +/- in a traditional auto
- open source design platform + crowdfunding

photo courtesy of Local Motors

Applications in medical products

- Healthcare is one of the fastest growing industries in 3D printing and developments in this sphere are expected to positively affect the safety, affordability and availability of health care.
- More than 80 FDA-approved products, including drugs
- Key applications
  - anatomical models
  - customized prosthetics
  - implants
  - pharmaceutical printing (customized dosing)
  - tissue and organ printing

- Does this signal the possibility of printing drugs at home? in the doctor's office? at a nursing home? in a hospital? at school? camp?
- Is the 3D printer a medical device?

Implications for the construction industry

- Borders between design, manufacture and construction will blur.
- 3D models will enable better communication between client and designer, resulting in less rework / waste of time / material.
- More freedom of design: component parts can be printed directly from the agreed design without the need to use mass produced building products.
- Innovative designs and customization will become the "new normal“ (the ‘wow’ factor)
- Can building materials – screws, nuts, bolts, beams, flooring, carpet, roof, etc. – be printed right at the construction site?
- A key challenge to make 3D printing more viable for construction is the ability to use a wider variety of materials due to the strength and durability required for buildings and structures.

Implications for the construction industry

- One company claims a single house measuring 33 x 132 x 20 feet can be constructed in less than 24 hours.
  - They fabricate individual components at their facility, ship them to the construction site, and then assemble the components.
  - They have also done a six-story apartment building.
  - 70% waste reduction and 50 – 80% labor cost reduction per building compared to the brick and mortar construction.
- The first 3D printed and fully functional office building >> 17 days
  - The offices, including all interior furniture, detailing and structural components, were fabricated using a 3D printer measuring 20 feet high, 120 feet long and 40 feet wide
  - Materials include a mixture of special reinforced concrete, glass fiber reinforced gypsum and fiber reinforced plastic

Photo courtesy of the Dubai Future Foundation

Food applications

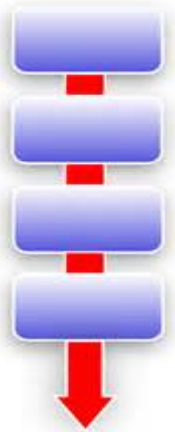
- It is feasible to produce carbs, protein and various types of nutrients in powder, pastes and oils, which can have a very long shelf life. These can then be printed to produce nutritious food with appropriate calorie levels >> customized nutrition
- What about printing food from insects? weeds? seeds? algae? Add flavorings for taste, the printer can make them look appetizing.
- What about people with specific needs? trouble chewing or swallowing, athletes, etc.
- As the world population grows and we deal with various types of disaster scenarios and health conditions we may need to change our view of what we consider to be food.
- Opportunities to reduce food waste.

Food applications

- A critical consideration for 3D food production includes features of machines, processes and finished products which meet FDA safety standards. These are developing, although more work clearly needs to be done.
- Many 3D foods are made with novel ingredients. For example, they may use binders for shape quality. These will need careful review.
- Many novelty products but companies in a ‘wait and see’ mode before they proceed with large scale commercial food product applications.
- Will food recall be a prominent early exposure?
- Will product defect suits rise with the introduction of home and commercial food printing units?

Product Liability in the United States: Does 3D Printing Change Existing Liability Analysis?

Mapping a product liability cause of action



Legal Theories for Product Liability
1. Negligence
2. Breach of Warranty
3. Strict Liability

*One who **sells** any **product** in a **defective** condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer or to his property if,*

*a) the **seller is engaged in the business of selling such** a product, **and***

*b) it is expected to and does reach the user or consumer **without substantial change in the condition** in which it is sold.*

Types of Defects:
1. Manufacturing Defect
2. Design Defect
3. Warning and Instruction Defects

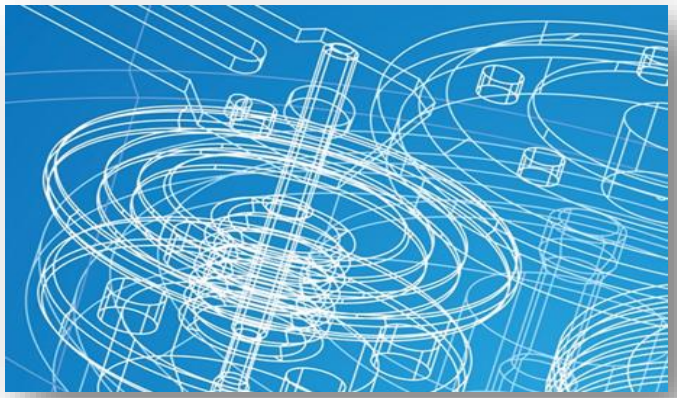
Manufacturing defect

- Did the manufacturer build according to specifications.
  - *Do specifications exist?*
  - *Who is making the specifications?*
  - *What testing is being done?*
  - *Was a change made in the supply chain?*
  - *Where is the ‘manufacturing’ in 3D printing?*

Design defect

Common Tests:

- Did the manufacturer use reasonable care in designing the product?
- Do the benefits outweigh the risks?
- Is the product more dangerous than the consumer would expect?
  - *raises the issues of who is a manufacturer? who is a designer?*
  - *with the intent to customize, who is responsible?*
  - *the standard legal tests remain the same but determination of legal fault becomes more complex.*



But ... is 3D printing a product or a service?

- If you **print a product** at a retailer are you buying a product or a service?
- If you **purchase a CAD design** to print something yourself are you buying a product or a service?
- Current analogies which are informative, but not absolute:
  - Architects and Engineers have long been providing CAD files; largely considered a professional liability design service.
  - Courts have often drawn the distinction between tangible and intangible products. (No strict liability for professionals).

Product liability avoidance: risk management practices

- CAD designers, printer manufacturers and sellers are attempting to limit their liability through disclaimers.
- Disclaimers range greatly in sophistication and detail. Nice to have but need to be careful on over-reliance.

Release of Liability Sample for CAD Design:

"Because the information set forth in the CAD Files can be modified unintentionally or otherwise—no representations or warranties of "fitness for a particular purpose."

"Design Builder" shall indemnify, defend and hold harmless the owner from all claims, damages, losses, expenses, penalties and liabilities of any kind...including attorneys' fees arising out of use of the CAD Files by the Design Builder or by third party recipients of the CAD files fro the Design-Builder.

Traceability is a key issue

- Large companies may have strong procedures in place for testing and use of 3D designs.
- But what about companies without rigorous existing use and testing protocols?
- What about industries that are not highly regulated?
- If the design cannot be traced to a responsible party, liability probably stops with the last entity in the traceable chain.
- Could lack of traceability (compared to current processes) increase exposure for identifiable defendants?
- Legal advice on warranties, conditions, implications of design change and contract language will be important.

Claims Scenarios

Expected loss scenarios

1. Workers exposed to printing materials

2. New material properties with unknown long term behavior (strength and durability)

3. Business interruption

4. Contamination and leaching (e.g. medical devices)

5. Adequacy of product testing

6. Intellectual property & cyber vulnerability

7. Product tampering

8. Product recall

Liability example scenario - construction

The structures of hundreds of houses are formed with 3D printed materials. The house leaches toxic fumes and the component materials warp causing the house to be uninhabitable.

- Who are the third party defendants? CAD designer, builder, manufacturer of building component, architect?
- What standards exist and will apply?
- What if someone customizes the original CAD design for the homeowner?
- What insurance coverages could be implicated? CGL, homeowners, professional liability

Liability example scenario – medical products

A jawbone is manufactured by 3D printing, the design is modified by the physician to customized specifications. The jawbone breaks a year later, leaches component material and causes an infection leading to the death of the recipient.

- Who are the third party defendants? CAD designer, jaw manufacturer, filament manufacturer, physician, hospital, the 3D printer?
- What insurance lines could be implicated? med mal, CGL, professional liability.

Allocation of liability and insurance considerations

- CGL policies: products and completed operations coverage is provided to insureds who manufacture or sell products
- Product liability is normally covered by a general liability policy and design services by a professional liability policy
- 3D printing, however, blurs the lines between what used to be more clearly separated between design work and production or manufacturing.
- This creates some gray area between professional liability and general liability policies.

Claims Handling

- What happens when property is lost, damaged or stolen?
- Can it be replaced via 3D printing? jewelry, for example
- One survey found that replacement is what insureds want the most
- One such service was nominated for two award categories at the British Insurance Awards 2016 (Claims Initiative and Technology)

Underwriting Considerations

Underwriting considerations - general

- Underwriting product liability has never been easy and that's not going to change
- Product liability constantly evolves and 3D printing may accelerate new changes.
- Underwriters need to follow the technology and ask more questions.
- Claims professionals need to recognize when a loss may be attributed, in whole or in part, to a 3D printing application, to provide this feedback to underwriters.
- Risk engineers need to keep up with emerging developments and uses for this technology and notify underwriters.

Underwriting challenges – product liability

- Rapid product development
  - adequate product testing?
  - trial and error hazard?
  - how to estimate sales and revenue projections?
- New companies/divisions with big ideas but no history
- Multiple sources of product liability
  - end products
  - printing machines
  - software
  - materials
- The specific binding material may be undisclosed as a corporate secret >> what products are we covering?

Underwriting challenges – premises liability

- Small fabrication operations (fabs) located, for example, at offices, retail shops, airports, hospitals, or other venues not formerly classified as 'manufacturing'
- Potentially hazardous materials >> worker and pollution exposure
  - plastics are relatively straightforward to work with
  - metals and ceramics are more difficult
  - slurries and gels are comprised of many different materials
  - living tissue and electronic materials are extremely difficult

Underwriting challenges – professional liability

- Intellectual property (most claims so far relate to IP and patents)
- Who is responsible for the design?
- Do the software and machine work properly?
- Where is the boundary with general liability?

Underwriting challenges – which concerns you the most?

1. Product liability
2. Premises liability
3. Professional liability

How do we underwrite these risks?

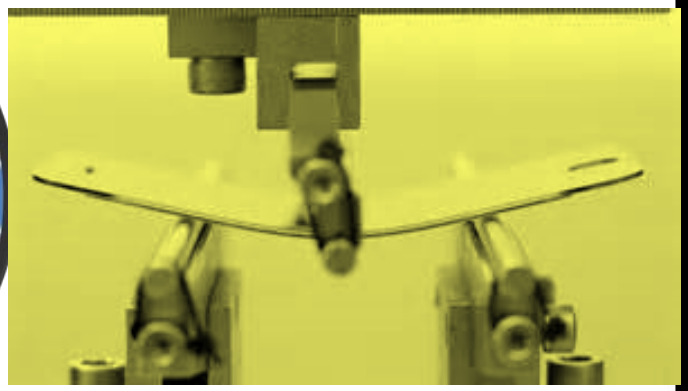
- This is an advance that we must embrace; important to note that it is a process not a product. Significant technology, research and investment is being applied. We are definitely going to see more risks with this type of exposure.
- Remember that there are many ways to describe 3D printing. Be watchful for this terminology so we know it when we see it.
- Each risk will need to be treated on its merits. We need to have an adequate understanding of the products being made and the implications of these if they become structurally instable. It is one thing if it is a toy but another if we are thinking about medical, construction or automotive parts.

How do we underwrite these risks? (continued)

- Some questions we can ask ourselves:
  - What are they making, what is the impact if these fail and cause injury or damage?
  - What is the production run? large batches or individual custom items?
  - What is the impact of the product leaching chemicals or the impact of pollution?
  - What is the appropriate exposure base (revenue projections)?
- Underwriters need to consult with risk engineering. As this becomes a more mainstream manner of manufacturing we are not necessarily going to be told that the process involves 3D printing.
- Creative and collaborative underwriting will be needed.
- We can not avoid this, we need to understand, underwrite and not ignore.

Underwriting considerations

- Perhaps the biggest uncertainty is the long-term durability of 3D printed products.
- Products made with 3D printers are in the midst of developing standards, specifications, testing and certifications, but only time will tell how well they will perform in real life applications.
- This is especially important for products used in critical commercial applications.



What should we look out for as underwriters?

1. prem op risks becoming products/manufacturing risks
2. start-up companies with new technologies
3. traditional ‘old school’ companies that are re-inventing themselves
4. new ways with old materials vs. new materials
5. critical safety products and applications

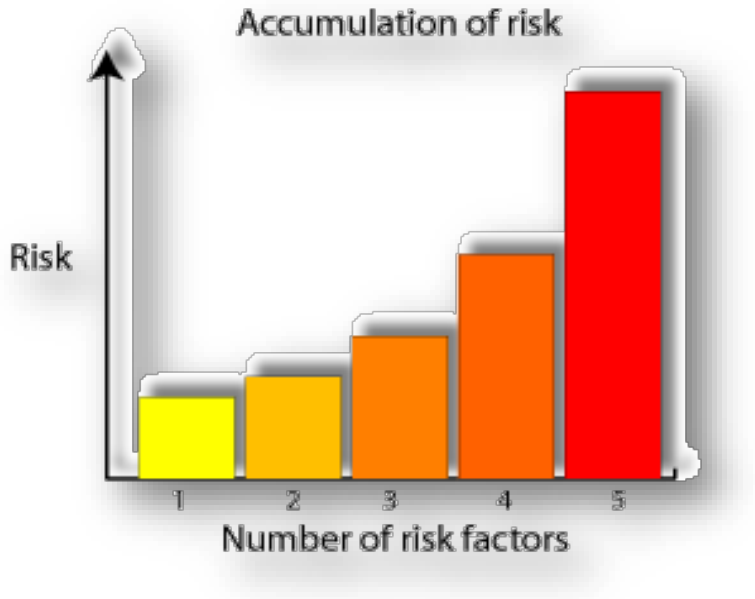
Impact on industry classifications for rating purposes

- What is the correct SIC code?
- Is there a 3D printing industry?
  - 2759 – Commercial Printing, Not Otherwise Classified
  - 3555 – Printing Trades Machinery & Equipment
  - 7372 – Services, Prepackaged Software
  - 3577 – Computer Peripheral Equipment, Not Otherwise Classified
- Is there a 3D printing industry? not really
- What is it being used for? what is it producing?
- What are the appropriate debits & credits?

There are real challenges in aligning the premium and the exposure.

Latency and accumulation

- There is no precedent for the long term use of any 3D printed product, both in terms of durability and inherent material risks.
- Accumulation potential:
  - Potential long-term unknown hazards
  - Risk of insuring multiple exposures in the supply chain
  - An undefined liability landscape which may (or may not) evolve unfavorably to insurers



Cyber exposure: a seemingly universal threat

- Cyber exposure applies to many classes of liability and 3D printing is at risk as a digital design and manufacturing medium >> shared platforms, e-collaboration, file transfer
- One of the unique challenges is controlling access to the original design and process software.
- Modification is expected so you can produce different types of products. This is one of the fundamental attributes of 3D technology.
- How to trace legitimate or unintended modifications?

Product liability benefits

- Are there features that make 3D printed products safer, stronger, better ... thus reducing exposure in the product liability landscape?
- Will customization make products more suited to their users? will this lead to less liability?
- Will the durability of existing products actually be exceeded by 3D products?
- Will there be fewer class actions based on non-commonality of the product and user?
- Will recall be a lesser issue due to ease of modification?

Ironic? the first 3D printing product liability litigation is against .....

- The printer.
- Makerbot, manufacturer of 3D printers, is alleged to have knowingly sold faulty printers. Class action suit filed alleging that Makerbot knew about poor printing quality and recurring problems. Subsequently dismissed but problems with the printer are well documented.
- 3D printer manufacturers as a separate high hazard exposure

- Allegations: "Defendants [knew] printers were severely flawed due to rampant quality control and product development issues at Makerbot."
- Seems that unit manufacturers may be the first in line for product defect claims.

An interesting claim question ....

Is damage to a prosthetic device property damage or bodily injury?

- a person's mobility assistance device was damaged by an airline; he was fully dependent on this device for mobility
- the airline offered $1500, the cost of a replacement
- the plaintiff argued the device was an extension of his body
- settlement was reached for $20k

Key lessons:

- 3D printing will make these devices more common
- will damage to them be treated as property damage or bodily injury?
- modern day prosthetics are not inanimate objects, they are complex devices that provide many services to the user

Conclusions

- Commercial applications already in use but long term acceptance not yet confirmed.
- Significant technology and investment is being applied so we expect to see a very rapid pace of change, especially with regard to the types of materials that can be printed.
- There will inevitably be unforeseen consequences.
- There are numerous underwriting challenges but we will certainly see more risks with this type of exposure.
- Look for benefits as well as risks.
- Our challenge is to understand and underwrite, not ignore.

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