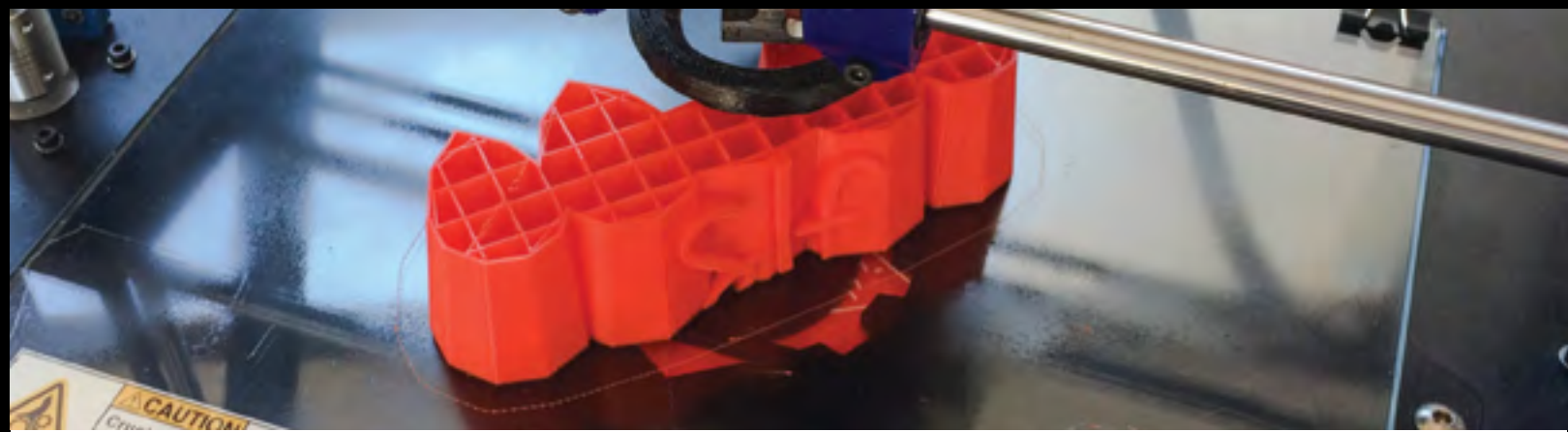


# Have your 3D printed cake and eat it too



# Insights for technology companies on 3D printing opportunities and risks

3D printing has the potential to change the way we produce and deliver physical products, the same way the Internet changed the way we interact with information. Products that formerly took weeks and months to design, prototype and manufacture, now take a matter of minutes. Shorter development cycles imply an exciting array of benefits for manufacturers of nearly any category of physical goods.

With the advent of 3D printing, manufacturers enjoy a shorter time to market and lower cost base, giving them a significant advantage over competitors using traditional manufacturing methods. Likewise, marketers can boost their brands with faster A/B split testing outcomes, resulting in better insight into buyer behavior and preferences. In healthcare, 3D printers can potentially save lives by creating human body parts injected with a patient's living cells. The possibilities truly seem endless.

But as firms scramble to take the lead in the 3D printing race, a word of caution is in order. There are pitfalls along the way that threaten to derail their revenue forecasts unless they protect themselves. Executives who understand these risks can position their firms to profit from this emerging trend.

## Mike Thoma

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- ▶ Four key risk categories for 3D printing that technology companies should understand
- ▶ Minimize exposure to key risk categories
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## Introduction

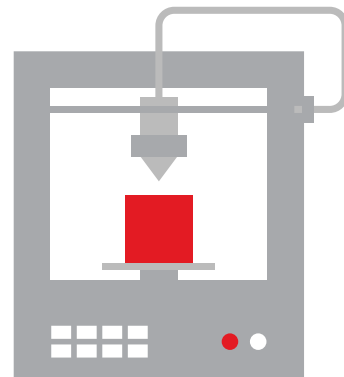
Picture a world where any hard goods can be produced on demand, in a matter of hours, at the exact location where they are needed. No ordering online. No shipping costs. No lengthy delivery or turnaround times. Just design the desired product on a personal computer, click an icon, and a machine generates the desired product in plastic or metal the same way an office printer produces documents on paper.

This may sound like fantasy technology found in a science-fiction movie. It's not. 3D printing, the technology of programming computers to produce real three-dimensional physical products, including human biological tissue, is not only upon us, but also represents an extraordinary business opportunity worth billions of dollars.

Along with the many opportunities, however, 3D printing also creates new risks for many types of companies, including:

- 3D printer device manufacturers and distributors
- Software engineering and design companies
- 3D printer feedstock suppliers
- Product manufacturers that use 3D printers to manufacture goods
- Distributors of goods manufactured using 3D printing technology
- Retailers of goods manufactured using 3D printing technology

In this issue of Travelers Technology Risk Advisor, we examine both the upside and the downside of 3D printing technology. First, we consider market size projections, identify key market drivers and review prominent 3D printing technology product categories. Then, we identify and explore specific risk classes impacting companies involved with this emerging technology, and we highlight for consideration several specific actions to minimize business risks. Finally, we conclude by sharing insurance considerations that firms should discuss with their independent agent or broker as they evaluate the 3D printing opportunity.



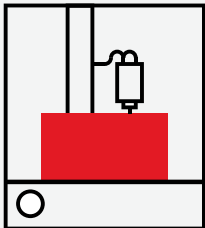


# Market size and drivers

3D printing, also called additive manufacturing, is already changing the way physical goods are developed, produced and distributed. While market size estimates vary, they uniformly indicate a large and growing market. Wohlers Associates, a technical and strategic consulting firm to the 3D printing industry, estimates the 2014 worldwide market for all additive manufacturing products and services at \$4.1 billion (with a 35.2% annual growth rate in 2014). A.T. Kearney estimates a \$4.5 billion global market for 3D printing hardware, supplies and services in 2014, growing to \$17.2 billion by 2020. And for certain applications, McKinsey Global Institute projects that 3D printing will have as much as \$550 billion of annual economic impact by 2025.

3D printing technology has been slowly but steadily evolving since its inception in the 1980s. Today, several key market drivers promise to increase the global impact of 3D printing. Companies that recognize and understand these drivers can position themselves to capitalize on this lucrative and expanding market. 3D printing creates several operational and business model advantages, driving broad market adoption of the technology across industry sectors (drivers 1-4). At the same time, industries are tailoring their application of 3D printing to their specific market needs (drivers 5-8).

## Drivers 1-4: 3D printing creates operational and business model advantages

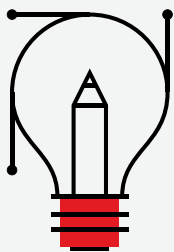


### DRIVER 1: PRODUCTION COSTS TRANSFORMED

With traditional manufacturing, companies can incur tremendous expense producing the very first unit of product, as major investments are required for complex or sophisticated manufacturing equipment. Marginal costs then decrease rapidly as additional units are produced. Manufacturers continuously try to lower production costs through a variety of measures like simpler product designs, cheaper raw materials and outsourcing labor to developing nations. These efforts, however, have not fundamentally changed the reality of high fixed costs to produce a first unit. As a result, CEOs have had no choice but to emphasize high production volumes: the more widgets you make, the lower the average cost per widget.

3D printing changes all of this – it dramatically improves the economic viability of low-volume production. Material and labor costs associated with aspects of component procurement, parts production, machining, welding and assembly can often be eliminated as a product moves directly from design to 3D production. With the flexibility of 3D printing, specialized products may be produced more cheaply than a traditional long production run of homogeneous units, requiring only a design file change.

For example, according to Dartmouth College Professor Richard D'Aveni, writing in *Harvard Business Review*, GE Aviation used 3D printing technology to reduce the production cost of a jet engine fuel nozzle by 75%. While the nozzle was previously assembled from 20 separately cast parts, the new process allowed fabrication in a single piece.



### DRIVER 2: ACCELERATED PRODUCT DEVELOPMENT

In manufacturing, time truly is money. The faster a company can release its products to the market, the greater their odds of gaining a profitable market share. Unfortunately, this goal often eludes manufacturers because conventional prototyping methods are slow, expensive and inefficient.

Because 3D printing is a toolless design method, it drastically reduces the time and cost to produce a prototype that traditional methods require. If a design doesn't work out, the firm has lost much less time than under conventional prototyping methods. Product engineers get feedback more quickly, allowing them to make more design enhancements to increase quality and marketability faster, greatly improving the odds of a successful product launch.

Fender Musical Instruments Corporation has improved its time to market by 30-40% for its popular Fender Slide Interface, thanks to its Stratasys Objet Eden350V 3D Printer. As Brian Ramey, Fender's Senior Industrial Designer, says, "If we didn't have a 3D printer, it would take a lot longer, and would be so much more expensive."



### DRIVER 3: PROFITABLE PRODUCT CUSTOMIZATION

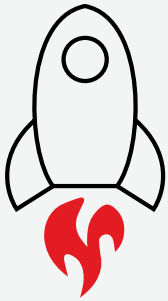
Fabricating products one layer at a time, 3D printing technology creates new opportunities for product customization and sophistication. By changing the production cost calculus, 3D printing also renders broader customization commercially viable. Manufacturers can generate more revenue by capturing more market niches, often also commanding premium price levels with more sophisticated design. In many industries, this design flexibility has been used to hollow out products, reducing product weight and materials costs. In a report on emerging technologies, the McKinsey Global Institute notes that the metal manufacturing industry uses 3D printing to create objects with an internal honeycomb structure, while bioprinting can create organs with an internal network of blood vessels.



### DRIVER 4: PRODUCT DISTRIBUTION ADVANTAGES

3D printing gives manufacturers new options for product distribution. Reducing product transport distance can save money and time, improving customer experience. When additive manufacturing technology evolves to accommodate stronger materials like steel, carbon fiber and titanium, 3D printers will generate entire finished products ready to be consumed at the moment and location they're printed. This could cause a massive transformation in global logistics. Instead of transporting finished goods as they do today, shipping companies may transport only raw material inputs for 3D printers. Local retailers and individual consumers need only to buy design files and materials for the products they want, then print the finished goods at their leisure.

## Drivers 5-8: 3D printing finds market-specific applications



### DRIVER 5: INDUSTRIAL PRODUCT APPLICATIONS

Manufacturing companies are experimenting with a variety of raw materials to print their products, including steel, titanium, aluminum and a variety of industrial grade thermoplastics. Many have gone beyond prototyping to use printed parts in their finished goods today. Ford Motor Company, for example, produces elastomer grommets for their electric vehicles and damping bumper assemblies for their work vans. "We're thrilled," says Ellen Lee, Team Leader, Additive Manufacturing Research at Ford. "The parts we've produced are mechanically strong, just like injection-molded parts. That's the target we've set for an automotive grade part."

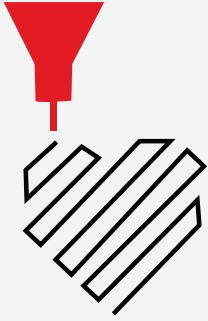
The aerospace and defense industries are also seeking ways to exploit the capabilities of 3D printing. Boeing fabricates plastic interior parts of Ultem (a high-performance flame retardant thermoplastic) and nylon in their test and evaluation units. Likewise, NASA is developing a land rover that could allow astronauts to explore extraterrestrial surfaces like Mars. Nearly 70 of the vehicle's parts were designed and built from production grade thermoplastics in the heated chamber of their Stratasys 3D printer.



### DRIVER 6: CONSUMER GOODS APPLICATIONS

3D printing is also on the rise in the consumer goods sector where the personalization trend continues to gain momentum. With 3D printing, consumers no longer have to sacrifice lower prices in favor of customization. Continuum, a San Francisco-based clothing retailer, lets Web customers design their own bikinis online. When a customer submits their design, a 3D printer prints the garment and ships it to the customer's address. Bringing the consumer into the design process encourages individuality, which, in turn, encourages brand loyalty. By creating products with 3D printers locally, clothing retailers may soon free themselves from dependence on labor from developing nations.

Additive manufacturing also benefits consumer goods companies by decreasing manpower necessary to produce prototypes and finished goods. Using conventional manufacturing techniques, Adidas required twelve technicians and four to six weeks to create a new shoe prototype. With their in-house 3D printers, product designers can evaluate the effectiveness of a new model in one or two days requiring only two technicians.



## DRIVER 7: MEDICAL AND HEALTHCARE APPLICATIONS

3D printing in the medical field started in the early 2000s with the development of custom dental implants. Today, 3D printers are being used to create hearing aids, contact lenses, and prosthetics made to an individual patient's exact body shapes and contours, often at a fraction of the cost of a conventional medical device.

Thirteen-year-old Dawson Riverman of Forest Grove, Oregon, was born missing two fingers. Unfortunately, his family could not afford a conventional prosthetic. Thanks to a volunteer organization called E-nable, Dawson now sports a fully functional 3D printed hand that enables him to ride a bike, grip a baseball bat, and try out for his school's soccer team. The cost? Less than \$50.

Bio printing, another emerging medical technology, may prove to be the most disruptive yet welcome technology of the 21st century. Researchers can now fabricate human tissue with 3D printers and a patient's own DNA. Using biodegradable scaffolds, doctors can print an organ's framework, then inject it with a patient's own living cells in the exact locations where they are most likely to grow naturally. Because the patient's own cells are injected into the bio printing material, the risk of rejection is minimized.

Though still years away, biomedical engineers hope to be able to print a customized liver, kidney, pancreas, or heart using bio-ink – a blend of living cells that a printer will assemble into living tissue layer by layer. If they are successful, it could dramatically decrease the mortality rate from chronic disease and render patient waiting lists a thing of the past.



## DRIVER 8: FOOD APPLICATIONS

Current 3D food printers may have limited capability, but that hasn't stopped companies from exploring new ways to produce and distribute their foods. In restaurants, a 3D printing can produce intricate desserts that would take a human chef more time than customers are willing to wait. Likewise, food industry experts expect 3D printers to eventually become as common in home kitchens as microwave ovens.

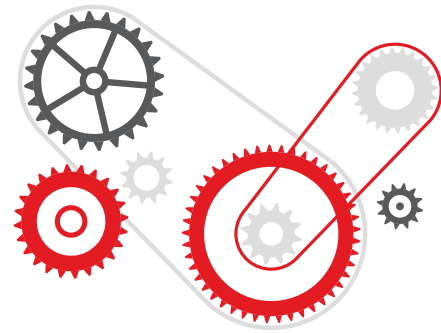
3D printing represents a potential shift in the business model of food service companies. As the technology matures, grocery stores may sell food cartridges loaded with edible 3D printing material for consumers to print and eat in their own homes.

The airline industry is interested in this concept. Today, meals must be pre-cooked on the ground before takeoff, so they are never truly fresh. Once they are loaded onto an airliner, they take up a great deal of space, which most commercial airliners don't have. A team of Indian engineers is trying to solve this problem with Sky Kitchen, an airborne 3D food printing system that can print ready-to-eat meals on demand. They are also developing software to allow passengers to choose their own meals from the touch screens in their seats.



# Key 3D printing technologies

Additive manufacturing represents a unique opportunity to breathe new life into U.S. manufacturing. Following decades of offshoring production processes, 3D printing has the potential to “re-shore” many categories of manufacturing. As President Obama said in his 2013 State of the Union address, additive manufacturing could “revolutionize the way we make almost everything.” Look for the following key 3D printing technologies to lead the charge.



## STEREOLITHOGRAPHY

Charles Hull, the inventor of 3D printing, designed this technique in the 1980s as a way to create plastic prototypes more quickly than the 2-3 month turnaround time legacy methods required. Stereolithography, often referred to as SLA, uses photopolymers, a type of liquid plastic that hardens when exposed to UV light. After reading the design file, the printer directs an internal laser to sculpt the object's first layer onto an elevator-controlled tray. After UV light harden the first layer, the printer submerges the tray for the laser to sculpt the next layer. The process repeats until the object is fully printed.

An SLA printer can produce objects of highly intricate detail not possible through conventional production methods. However, it only makes economic sense for single-unit prototyping or very short production runs. Although Mr. Hull invented the technique for industrial use, he is more excited about SLA's possibilities in the medical and healthcare fields. “Life saving and surgical planning procedures, all the way through dental applications – these are things I really hadn't thought of when I invented 3D printing.” Popular SLA printers include the iPro 8000 and the ProX 950 from 3D Systems, Inc., the company Hull founded.

## FUSED DEPOSITION MODELING

Scott Crump created fused deposition modeling (FDM) and went on to found Stratasys, Ltd., a major vendor of 3D printers featuring this technology. FDM relies on extrusion, an industrial technique in which melted plastic is forced into a die to shape it into a continuous thread or filament, after which the machine cuts it to the desired length. Each succeeding layer binds to the one before it as it cools, but unlike stereolithography, FDM doesn't require UV light. FDM printers are the most affordable on the market today, which explains why they are the most pervasive.

FDM's advantage over stereolithography is the strength of the printed product. FDM printers can produce high-performance thermoplastic parts structurally sound enough for industrial grade applications. Automaker BMW was able to reduce the weight of one auto part by 72 percent using a Stratasys FDM Production Series printer. The technique is also popular with consumer goods makers like Black & Decker, Dial, and Nestlé. If there is a downside to FDM, it is the target object's surface quality. FDM requires greater force to fuse layers together, which often degrades surface smoothness, making stereolithography a better choice when visually pleasing aesthetics are more important than industrial-grade chemical composition.



## SELECTIVE LASER SINTERING

Selective laser sintering (SLS) forms objects from tiny particles of glass, nylon, and even food-grade ceramic material using atomic fusion. Its sister process, direct metal laser sintering (DMLS), does the same using powdered metals. The printer traces a cross-section of the desired object in powder form. A laser then heats the powder to just below the boiling point (sintering) to form a solid. When the last layer is printed, the finished product is left to cool inside the machine.

Like stereolithography, SLS produces production-grade parts right out of the machine. Additional finishing or sanding is seldom required. It also doesn't require additional scaffolding to support the object during printing. This results in faster print times and less waste, making SLS a good choice for creating final products as well as prototypes. SLS is very popular in the aerospace industry where aircraft are built in small numbers and remain in service for a long time. It also works well for medical/healthcare items like prosthetics, hearing aids and dental retainers.

SLS combines the best of SLA and FDM together in one process. Because of the high-powered precision lasers involved, SLS printers like 3D Systems' Vanguard Si2 and Sinterstation HiQ and Pro are generally more expensive than those using other techniques. But for high-speed, production-quality 3D printing, SLS is an excellent choice.

## INKJET BIOPRINTING

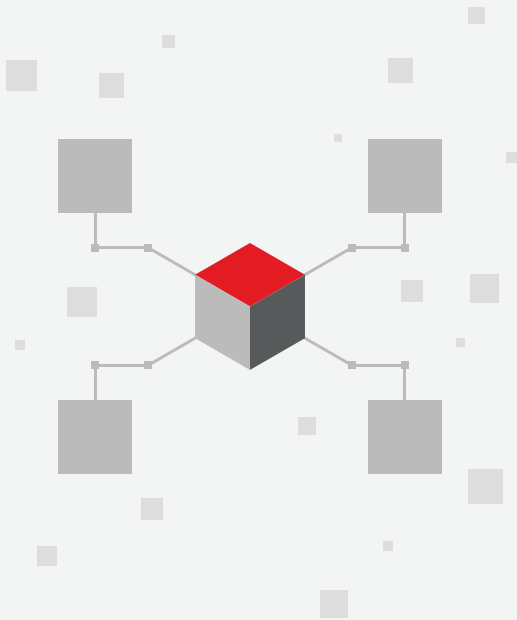
Bioprinting could well be the technological answer doctors have been looking for as they explore the possibilities of regenerative medicine. Biomedical engineers can blend living cells into a 3D printer input called bio-ink. The printer then reads the customized patient-specific CAD file to produce living human tissue in the patient's exact required dimensions, greatly increasing the odds of a successful implantation. If scientists can enable these printed cells to accept a patient's natural blood flow, 3D printers may become as commonplace in modern hospitals as EKG units and X-ray machines.

## OTHER 3D PRINTING PROCESSES

Other less pervasive 3D printing techniques are also used in manufacturing sectors. Some of these processes have yet to gain mind share within the 3D printing community. Others combine the basic processes outlined above. Still others defy categorization altogether.

- **Laminated object manufacturing (LOM).** This involves fusing or laminating together layers of plastic or paper with pressure and then heat, followed by cutting a product into a required shape with a computer-controlled laser or blade.
- **Digital light processing (DLP) projection.** Using a small vat of liquid photopolymer, a projector solidifies an entire object layer on the bottom of a platform that is incrementally raised rather than lowered. Many think of it as "inverted" stereolithography.
- **Binder jetting.** This process uses powder and a binding material. After each successive layer, the printer shoots a layer of binding agent, which acts like super glue between product layers until all layers have been printed.
- **Photopolymer jetting.** Combining stereolithography and binder jetting, the printer deposits a thin layer of plastic module platform similar to SLS. Each successive layer is exposed to UV lamp to cure the plastic together. Parts are not durable over time and have limited mechanical properties.
- **Food extrusion printing.** Borrowing techniques from other 3D printing processes, food printers extrude culinary creations from edible ingredients packed in stainless steel capsules. One challenge they'll have to overcome is temperature. Unlike plastics, each printed food material could have a different melting point for every ingredient required.

## Four key risk categories for 3D printing that technology companies should understand



**3D printing is gaining momentum in the global marketplace. Manufacturers are finding ways to decrease costs and improve product quality. Hospitals and healthcare professionals will improve patients' quality of life or even save lives. Food companies will open new markets for encapsulated meals that consumers can print and eat in their own homes.**

But as the technology continues to advance, so do the inherent risks. Everyone in the entire global supply chain should understand the risks and minimize them. Should a 3D printed part or food cause injury or illness, it could result in a financially devastating lawsuit. Therein lies the challenge: the field is so new, no one is sure how liable they really could be.



## Category 1: Property damage risk

Property damage risk refers to the risk of physical damage to, or loss of use of, tangible property caused by a party who is not the property owner. Such property can include real property and personal property. If a 3D printed object causes property damage due to a defect or a failure to function as intended, a lawsuit could result. Any party involved in the product's manufacturing or distribution chain could find themselves named as a defendant.

### ILLUSTRATIVE PROPERTY DAMAGE RISK SCENARIOS

- **Fire and smoke damage.** A medical device company in leased manufacturing space 3D prints orthopedic appliances they intend to ship to distributors. However, a band holding several wires within the printer breaks, causing the wires to fall too close to the printer's heat source and to ignite it. The ensuing fire causes smoke damage to other tenants' property.
- **Damage from pipe-fitting failure.** A regional airport buys a refueling truck equipped with a high-pressure hose and 3D-printed pipe fittings. During a refueling operation, one of the fittings breaks, causing thousands of gallons of jet fuel to spill onto the tarmac and run into the airport grounds, physically damaging the landscape. It was later discovered that the pipe fittings were not designed to withstand required pressure levels. The airport authority sues the pipe fitting manufacturer and the product designer for the costs of lost fuel and landscape restoration.



## Category 2: Bodily injury risk

Even though few bodily injury cases involving 3D printed products have gone to court, claims experts are relatively sure that liability will fall upon any of three possible parties: the product designer, the manufacturer who printed the product, or the raw material (feedstock) supplier. Depending on the magnitude of the claim, the damages could cause serious financial hardship to parties found liable. Any of the following scenarios could form the basis of a liability lawsuit:

1. **Defective design.** The products are engineered with a design so hazardous that a reasonable person could use the device as instructed, yet still suffer bodily injury. In 3D printing, this could mean that the 3D printed product was poorly designed, or the designer engineered the products in a substandard way.
2. **Defective manufacturing.** The products are either manufactured improperly or damaged in a way that prevents their proper use. This defect can occur at any point between the factory and the place the user receives the product. This could also occur if the 3D printer feedstock was defective in some way.
3. **Defective marketing.** The products are designed and manufactured properly, but the user isn't properly instructed on how to use the device properly or warned about the dangers of using it improperly. This could mean that the 3D product manufacturer's documentation was incorrect, leading to incorrect usage.

### ILLUSTRATIVE BODILY RISK SCENARIOS

- **Choking hazard.** A 3D printer is intended for metals manufacturing but can also be used for plastics. A parent buys a toy for her 2-year-old child that contains 3D printed parts. As the child plays with the toy, one of the parts breaks off. The child inserts the part into his mouth, causing him to choke. The parent sues the manufacturer of the printer in a "failure to warn" product liability suit, claiming that the warning label was not conspicuous enough for an average user to notice.
- **Prosthetic failure.** A patient with a prosthetic leg falls down a flight of stairs, injuring himself. The ensuing investigation shows that a 3D printed part of the knee assembly broke due to production defects before it left the factory.
- **Bio printing rejection.** A patient has to have a section of his trachea removed due to lifelong smoking. After taking measurements, the hospital builds an exact replica of the missing section using 3D bio printing. However, a bug in the printer's firmware causes it to misread the CAD file, causing the resulting trachea section to be produced with an invisible toxic petroleum-based coating. The patient dies because his body rejects the part, which inflames the trachea and completely blocks the airway. The patient's family sues the hospital for wrongful death.
- **Food borne illness.** A restaurant purchases a 3D food printer to serve more uniquely designed desserts. However, restaurant staff doesn't clean the printer according to the instructions causing bacteria to grow in the deep recesses of the printer. Patrons who ate the desserts came down with a food borne illness that experts attribute to 3D food printing.



## Category 3: Technology Errors and Omissions risk

Despite a manufacturer's effort to develop and sell an effective product customers will enjoy, things can go awry. In addition to bodily injury, a company can be held liable for an economic loss from the failure of a printed product to work as intended, due to an error, omission or negligent act.

High-profile product failures can destroy a customer's business continuity and damage a printer maker's reputation. Executives who understand this risk category can better protect their companies from these claims. The following scenarios illustrate how 3D printer makers, manufacturing companies, and feedstock suppliers could be held liable for a catastrophic failure of either their printer or the products built with it.

### ILLUSTRATIVE TECHNOLOGY ERRORS AND OMISSIONS RISK SCENARIOS

- **Product malfunction.** An electronics manufacturer uses 3D printed components in its consumer electronics products. The products failed to perform as warranted, leading to media coverage and tarnishing the company's reputation for high quality products. The story hits the news media, leading to a loss in revenue over the following year. The electronics manufacturer sues the 3D printer manufacturer for such loss.
- **Business disruption.** An e-commerce retailer invests in web servers built with 3D printed circuit boards. Several of the boards fail during the holiday season due to heavy customer traffic, causing service outages and lost revenue. The retailer sues the server vendor, the printer maker and the chip designer for seven-figure losses.
- **Tarnished reputation.** A world-renown orthopedist known for developing highly customized orthopedic implants for extremity surgeries purchases and uses a new 3D printing device. Due to a programming error, the device prints defective orthopedic implants, resulting in several high-profile patient device failures. The resulting publicity results in the orthopedist claiming reduced in-patient census. He sues the 3D printing device maker for economic losses.



## Category 4: Cyber and intellectual property risk

Industry experts classify cyber risk as the potential financial loss, reputational damage or business interruption due to improperly secured data held within information systems. It can occur as the result of a cyber criminal's attack, ineffective IT department policy, IT security software failure or even damage from disgruntled employees.

Many people mistakenly think that companies involved in 3D printing are not susceptible to cyber risk if their printed objects contain no electrical components. However, any 3D printed product must be designed using CAD software, which produces files that may contain proprietary information. If those files are lost or stolen, it could spell disaster. Therefore, any company using 3D printing should protect its intellectual property by adopting effective IT security measures to protect against computer-based threats.

### ILLUSTRATIVE CYBER AND INTELLECTUAL PROPERTY RISK SCENARIOS

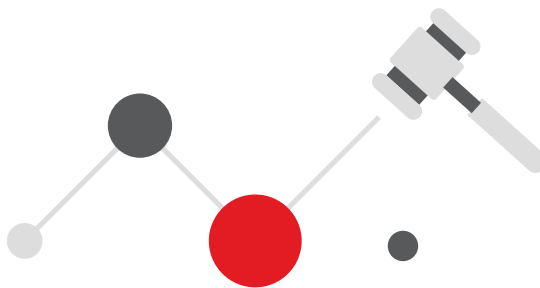
- **Cloud data breach.** A medical device company outsources production processes to a contract manufacturer who employs 3D printing to produce some tools. After receiving the design files, the manufacturer distributes the designs to its remote production sites in cloud data storage. A skilled hacker penetrates one of the remote sites' firewalls to steal the technical design files. Soon afterwards, "look-alike" products are released to market at a cheaper price. The medical device company sues the manufacturer and 3D printer maker.
- **Digital sabotage.** A hacker breaks into a 3D printing contract manufacturer's data stores and accesses customers' product design CAD files, purposely damaging them by changing critical values within the design files. The manufacturer's next production run produces thousands of substandard parts, which cannot be used by customers, resulting in a claim for economic loss. The contract manufacturer is sued for damages resulting from the failure to protect the CAD files.
- **Design theft.** A disgruntled employee takes fabric designs from his former employer to a textile company employing 3D printing technology. Representing the designs as his own, the former employee hires the textile company to replicate the fabric design, which he then sells in direct competition with his former employer. The employee's former employer sues the textile company for copyright infringement.
- **Network penetration.** A company connects its new 3D printer to its local area network (LAN). However, network administrators failed to apply the same security standards to the 3D printer as they do other nodes in their network. A hacker introduces a virus into the company LAN through this vulnerability, causing a business interruption and economic loss due to excessive downtime. The company also incurs costs to remove the virus and repair damaged software.





# Minimize exposure to key risk categories

3D printing offers companies and consumers virtually limitless possibilities for creating nearly any kind of hard good imaginable. But this freedom comes with a sobering caveat. Should a 3D-printed product be found to cause physical or financial harm to someone, a costly liability claim may follow and any companies or individuals in the chain of manufacture and distribution may have to defend themselves in court.



## PROPERTY DAMAGE & BODILY INJURY RISKS

## SOLUTIONS

### Actions to consider for minimizing bodily injury and property damage risk

Manufacturers, software designers, distributors/retailers and companies providing component parts or raw materials bear a responsibility to ensure that property damage and bodily injury do not result from the use of 3D printed products. Therefore, it is crucial that these companies prepare for all possible outcomes from a user's experience, including class action or mass tort lawsuits due to bodily injury or property damage risks. Direct and reputational costs from product liability events can cripple companies, sometimes endangering their very existence.

Companies should consider the following steps to help minimize exposure to both property damage risk and bodily injury risk. Please note that the following points should be taken only as guidelines, not as an exhaustive list.

- **Conduct robust hazard analysis.** Methods such as fault tree analysis (FTA), failure mode and effects analysis (FMEA), and hazard and operability analysis (HAZOP) can be used by both 3D printer manufacturers and product manufacturers to assess potential device hazards at different points in the 3D printing development and commercialization processes. These can involve identifying the major components and operating requirements (e.g., raw materials, hardware, device interfaces, operating software, services and the operating environment), and then identifying potential hazards for each. Hazards can include anything from toxicity and flammability, to unsafe construction, to mechanical or choking hazards. Companies should not ignore issues that can be introduced during processes such as manufacturing, packaging, labeling, storage or transport.
- **Conduct routine design reviews.** Firms involved in 3D printing should assess the likely frequency and severity of all identified potential hazards their devices could cause. All firms in the 3D printing chain should seek to eliminate high-severity hazards and eliminate or reduce the potential for medium and low-severity hazards. Companies should assemble a diverse team that includes personnel outside of the design process to generate potential mitigation solutions. They can task the solutions team with considering how specific hazards have been mitigated for analogous industries or device categories. If possible, manufacturers should invite printer makers and product designers to these meetings when high-risk products are being reviewed.
- **Build in cybersecurity.** As metals become more widely used as input materials, 3D printers will be more commonly used to produce electronic data components for industrial, household and medical applications. Where appropriate, manufacturers and product designers should provide locking mechanisms on devices and communication ports to prevent tampering. They should also protect critical functionality by issuing a warning when a device's cybersecurity is compromised.
- **Conduct extensive testing.** Product manufacturers should not only test their own 3D printers and build systems, but also any peripheral hardware they may be using. Feedstock providers should also insist that all input materials undergo testing procedures for proper chemical composition. This is particularly important for chemical components purchased overseas where local regulations may not be as stringent. Likewise, product designers should make sure their 3D printed products meet the same rigorous testing requirements as those built with conventional manufacturing techniques.

- **Evaluate awareness of and adherence to key standards.** The manufacturer should ensure that all relevant personnel are aware of and adhere to applicable standards. Several independent standards organizations publish standards to establish safety and conformity of products and processes, many of which apply to 3D printing. For example,
  - ANSI Z535 – presentation of safety and accident prevention information (industrial and other manufacturing).
  - ISO 14971 – application of risk management for medical devices.
  - Underwriters Laboratories (UL) – 3D Printing & Additive Manufacturing Equipment Guideline.
  - Consumer Product Safety Commission regulations (consumer goods).
  - National Fire Protection Association guidelines.
- **Develop clear safety and use instructions with conspicuous warning labels.** Companies can provide users with clear, unambiguous written instructions on the full range of use for 3D printed devices. The company can:
  - Include visual depictions of proper device use.
  - Incorporate information on proper storage and transportation if applicable, as well as instructions on what to do if a device malfunctions.
  - Anticipate ways in which the products can be used for other-than-intended purposes, and provide warnings for user scenarios that should be avoided. Any 3D printed item that could become a choking hazard needs a warning label. Small children are notorious for inserting small items into their mouths, potentially blocking the airway. This applies to designers and makers of any consumer goods (not just children's toys).
- **Chemical makeup quality control.** In order to ensure that a 3D printed part will perform properly for its intended purpose, manufacturers should collaborate with feedstock providers on chemical makeup testing procedures. Conventional chemical analysis techniques include chromatography, spectrometry, thermal/elemental analysis, and polymer molecular weight characterization. If in-house resources are unavailable, company leadership should consider outsourcing these procedures to a reputable third-party chemical quality control firm.
- **Implement effective maintenance.** When operating 3D printers for food or bioprinting, print areas and printer heads must be thoroughly cleaned and any residual substances must be removed to avoid contamination of the next print run. This should be done after every print run, even if there is no visible printing material in the work envelope (where the printer layers the product).
- **Well-documented compliance.** In markets with stringent government regulations, manufacturers and feedstock providers should implement compliance documentation procedures. For high-volume operations, manufacturers should consider investing in software components that automate the compliance documentation process. Many such packages can produce compliance reports for impromptu visits by inspection agencies.



## Actions to consider for minimizing Technology Errors and Omissions (E&O) risk

Companies can minimize Technology E&O risk by implementing many of the previously highlighted suggestions for property damage and bodily injury risks. Sound information security practices, effective virtualization and clearly documented operating instructions are highly recommended.

Contract practices can impact technology E&O risk, and much of a company's exposure can be mitigated by protective language in its end-user license agreements (EULA). To help manage exposure, companies should evaluate the following customer contract provisions:

- **Limitation of liability.** This provision disclaims liability for certain types of damages – usually incidental, consequential or special damages. In the event of threatened litigation, these provisions can become very useful.
- **Damage caps.** These provisions limit the amount of recoverable damages. The limitations can be defined in terms of a specific dollar amount or an amount to be determined, depending on specific factors set forth in the contract.
- **Disclaimer/limitation of warranties.** This provision identifies the warranties provided, disclaims or limits those warranties not provided, and identifies the remedies available in the event the product or work does not comply with the warranties provided.
- **Integration.** This provision identifies the documents that comprise the parties' contract and will also limit the parties' reliance on documents and information outside of the contract.
- **Contractual risk transfer and defense/indemnity provisions.** Provisions like these can shift risk to other parties.



## Actions to consider for minimizing cyber and intellectual property risk

Many companies connected with 3D printing underestimate cyber risk since their printers produce only physical goods. But in today's hyper-connected world, 3D printer makers, manufacturing companies, and feedstock providers must be vigilant to protect against the possibility of a devastating lawsuit resulting from data compromise involving the use of this new, powerful technology. Companies should consider the following steps to help minimize exposure to cyber risks:

- **Secure 3D printers.** Companies who connect 3D printers to their LAN must understand that the printer is a node just like any other, and must be secured. Companies should either secure these machines with adequate security software or separate the printer from the network altogether.
- **Encrypt critical data elements.** 3D printing brings with it a scary dynamic that manufacturers have never had to deal with before. For the first time, a company's proprietary competitive advantage can be stored in one single computer file that can be stolen. That is why it is so crucial for companies to encrypt their CAD files with the strongest encryption algorithms available to prevent cyber theft.
- **Secure the cloud.** Cloud data storage has gained widespread adoption as a cost-saving mechanism. However, CIOs shouldn't blindly trust a cloud provider's security claims. They should insist on seeing written security procedures, and if possible, visit the provider's premises to ensure those procedures are being followed.
- **Virtualize.** CAD files are often transmitted from an engineer's desktop to a secure private cloud within the company's firewall. Virtualized clouds can secure data with multiple diverse operating systems, each operating within a different security context. Banks often secure depositor payment details this way; 3D printing makers and manufacturing companies should consider similar functionality.
- **Verify intellectual property rights.** Product designers often create their own CAD design files and approach contract manufacturing firms to produce their products for them. But just because a CAD file represents that designer's idea doesn't mean the idea is original. Contract manufacturers using 3D printers should take steps to verify that the designs provided to them don't violate any patent, copyright or other intellectual property laws. Additionally, manufacturers should consider insisting that their customers agree in writing that their designs are their own and that they will hold the manufacturer harmless and will defend and indemnify it in the event of an intellectual property claim against it.








# Insurance considerations for 3D printing

Because the 3D printing field is just getting started, printer makers and contract manufacturers that use them face unique challenges as they move forward into the 3D printing revolution. As more companies adopt this exciting new technology, more product liability cases are certain to make headlines, showing manufacturers where they are most vulnerable. Until then, companies involved with 3D printing technology are unlikely to fully understand and eliminate their current or emerging exposures.

As always, safety features, data protection measures, effective contract risk management and good design decisions can help companies reduce their exposure to some of the risks we see today. But with every emerging technology comes risks we don't yet see. To help manage exposures to both of these types of risks, companies should investigate their insurance options for the categories of risk described in this issue of the Technology Risk Advisor series, as indicated in the following table:

		
Risk class	Illustrative risk scenarios	Relevant insurance coverage to evaluate with an agent or broker
<b>Property damage</b>	<ul style="list-style-type: none"> <li>• Fire and smoke damage</li> <li>• Damage from pipe-fitting failure</li> </ul>	<b>Products liability coverage</b> provides coverage for physical damage to, or loss of use of, a third party's tangible property arising out of a product manufactured, sold, handled, distributed or disposed of by a named insured.
<b>Bodily injury</b>	<ul style="list-style-type: none"> <li>• Choking hazard</li> <li>• Prosthetic failure</li> <li>• Bio printing rejection</li> <li>• Food borne illness</li> </ul>	<b>Products liability coverage</b> provides coverage for physical harm to a person arising out of a product manufactured, sold, handled, distributed or disposed of by a named insured.
<b>Technology errors and omissions</b>	<ul style="list-style-type: none"> <li>• Product malfunction</li> <li>• Business disruption</li> <li>• Tarnished reputation</li> </ul>	<b>Errors and Omissions (E&amp;O) liability coverage</b> protects against damages that you must pay because of economic loss resulting from your products or your work and caused by an error, omission or negligent act.
<b>Cyber and intellectual property</b>	<ul style="list-style-type: none"> <li>• Cloud data breach</li> <li>• Digital sabotage</li> <li>• Design theft</li> <li>• Network penetration</li> </ul>	<b>Information security coverage</b> provides coverage for critical cyber risks. Coverage options vary, but most include network and information security liability, and communications and media liability. Firms can also opt for many first-party expense reimbursement coverages including data restoration, business interruption, computer and funds transfer fraud, crisis management and security breach notification expenses.

## Circumstances vary, and all risks may not be insurable.

It is important to contact your independent insurance agent or broker to make sure you get the right coverage and services for your company.



# Risk expertise for the technology industry



Travelers has been insuring technology companies for more than 30 years. Hear directly from travelers technology industry experts, using the links below.



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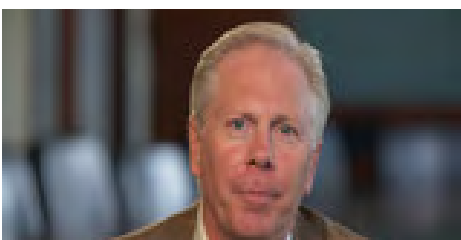
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# How Travelers can help

Travelers has been protecting technology companies and new technologies longer than most insurance companies and we understand the unique needs of everyone involved in the 3D printing ecosystem, from printer makers, to manufacturing companies that use printers, to the individual printer owner trying to launch a new company or invention. As printer makers work on the next groundbreaking 3D printing technology, Travelers will be there to help manage their risks with the right insurance products and services.

Travelers stays ahead of technology industry risk. From the rise of PCs, to the Y2K scare, to the Internet economy, Travelers continues to evolve with effective coverage options to provide technology companies with important insurance coverage for exposures as they continue to innovate.



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**Mike Thoma**, Chief Underwriting Officer,  
*Travelers Global Technology*

3D printing stands poised to completely revolutionize the way we make and consume manufactured goods. Rely on Travelers’ experience and innovation as you boldly capitalize on what is certain to be a lucrative game-changing opportunity.

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