



Consumers' Research

established 1929

Bulletin • Fall 2015

Approval Purgatory: 23andMe and FDA Restrictions on Consumer Agency

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Racing into a Driverless Future

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New Immunotherapies Hope to Transform Cancer Treatment

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Consumer Protection is Worth an Extra Second

Joe Colangelo

GM Recall in Review

Millan Bederu & Kyle Burgess

23andMe and YOU*



- 1 *Blasting the Past, Preserving the Present*
- 2 *Racing into a Driverless Future*
- 4 *Encapsulating the New Fountain of Youth*
- 6 *Emerging from the GM Ignition Switch Recall*
- 8 *Global Integration Calls for Open Collaboration*
- 10 *New Immunotherapies Hope to Transform Cancer Treatment... If We Can Afford Them*
- 12 *Approval Purgatory: 23andMe and FDA Restrictions on Consumer Agency (Editorial)*
- 14 *TSA Pre-Check Makes Screening Faster, But Maybe Not Safer*
- 16 *Consumer Protection is Worth an Extra Second at the Register (Editorial)*
- 18 *Bitcoin and the Collaboration Age: The USDOJ West Coast Digital Currency Summit*

Table of Contents

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Consumers' Research is an independent educational organization whose mission is to increase the knowledge and understanding of issues, policies, products, and services of concern to consumers and to promote the freedom to act on that knowledge and understanding.

Consumers' Research believes that the cost, quality, availability, and variety of goods and services used or desired by American consumers—from both the private and public sectors—are improved by greater consumer knowledge and freedom.

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Research
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Blasting the Past, Preserving the Present

Brief “tidbits” on Products and Consumer Affairs Then and Now

Whatever Happened to Saccharin?

WIn June 1974, CR reported on recent animal studies that suggested America’s favorite sugar substitute, saccharin, may cause bladder cancer if consumed in large quantities. Congress subsequently mandated further study of the sweetener and required that all products containing the substance bear the warning: “Use of this product may be hazardous to your health. This product contains saccharin, which has been determined to cause cancer in laboratory animals.” As it turns out, the mechanism by which saccharin causes bladder cancer in rats is not relevant to the human anatomy. Later studies showed no consistent evidence that saccharin causes cancer in humans. Coincidentally, however, saccharin was listed on the U.S. National Toxicology Program’s Report on Carcinogens as a “substance reasonably anticipated to be a human carcinogen” in 1981, the same year that aspartame was officially approved by the FDA as a “safe” substance. Ironically, later studies also showed a link between aspartame and cancer in rats but no link has ever been established in humans. By the time saccharin was delisted as a potential carcinogen in 2000, aspartame had risen to dominance in the market for sugar substitutes under brand names such as NutraSweet and Equal. Today saccharin is used in various food products, including Sweet’N Low and sugar-free gum.

Novel Techniques for Discouraging Burglars

Also in the June 1974 issue, CR offered a few uncommon tips to prevent your home from being burglarized while you were away. Some still seem like sensible ideas, such as asking a neighbor to use your garbage can or to park in your vacant driveway. Keeping tools and ladders locked up in your home or a shed was also a recommended break-in prevention tactic. Another idea, however, would appear somewhat odd to readers today. The suggestion was to “bury the telephone under several pillows so that the persistent ringing of an unanswered phone [would] not alert a prowler to the existence of a clear field for his operations.” One might say a better solution would simply be to unplug your phone. But it is easy in our technologically advanced era to forget that home phones were initially connected to wall outlets with

cords that did not detach and therefore could not be easily turned off. Unlike 1974, when corded home phones and pay phones were the only means of calling somebody, 45 percent of households today do not even possess or use a fixed-line telephone. By contrast, Pew Research Center found in 2013 that 91 percent of adults in the U.S. own a mobile phone. But even those who do still have a home phone likely won’t need to bury it in a pillow while they are away, since today’s models are easy to turn off or unplug.

Metric Garment Sizing?

Speaking of blasts from the past... remember when the United States was planning to convert to the metric system back in the '70s? At the time, CR expressed concern over how difficult it would be for women and girls to learn new metric garment sizes after having only experienced American sizing, which generally came in seven classifications: Junior Petite, Junior, Misses Petite, Misses, Misses Tall, Women, and Half-Sizes. As CR pointed out, these are general body sizes rather than actual dress dimensions, and a woman would have to learn from experience which size fit her best. These sizes would typically range from 3 to 15, 4 to 16, and so on, but the practice of “vanity sizing,” or using smaller numbers to make clothing more appealing to consumers, was already well-established in the garment industry. Men’s clothing, by contrast, would typically be sized by neck and arm dimensions, or on a much simpler scale of small, medium, large, and variations thereof. When the metric system went into effect, however, the switch from body sizing to dimensional sizing in women’s clothing would have meant that a size 10 would become a size 36, for example. The piece concludes that, “It will take quite a bit of doing to make metrication popular in the garment trade and with garment purchasers in the United States.” As it turned out, the process of metrication was more or less abandoned over the following decades and American consumers did not have to grapple with the more involved (and less appealing) garment sizing after all. ◀

Racing *into* a Driverless *Future*

Mackenzie Evans

Imagine that it is 7:00 am on Monday morning and your alarm clock is blaring. You awaken, quickly pack lunches for the kids, and wave them off from the kitchen as your family's self-driving vehicle carts them off to elementary school. Fifteen minutes later, the vehicle returns itself to your townhouse to transport you to work. Hot coffee in hand, you begin your commute into the city flipping through the news on your tablet. You even have time to answer a few emails before your vehicle stops in front of the entrance to your office building twenty minutes later. You feel rested, relaxed, and ready to be productive. You smile, knowing that you will receive commission for the dozen trips that your vehicle is scheduled to take today, transporting other people to and from places like doctor's offices and grocery stores. When 5:00 p.m. rolls around, your vehicle will be waiting for you with tonight's take-out dinner in the backseat and a glass of wine in the cup-holder.

With a \$42 billion global market expected by 2025, autonomous cars will potentially have a widespread impact on society. If advancements continue at the current rate, vehicles that drive themselves on the freeway or take over in traffic jams may be on the road as early as 2017. What impact could this transition to autonomy have on the average U.S. consumer, and our world as a whole?

Many vehicles already feature technology that allows cars to perform automated tasks such as parallel parking. Automakers around the world are building off these developments and racing to build cars that drive with limited (or no) assistance from humans. Industry giants including Audi, Tesla, Nissan, BMW, and General Motors have launched dozens of projects centered on developing autonomous driving. Google's self-driving fleet already has over 1.7 million miles on the road. Reports indicate that these cars will be able to navigate crowded city streets by 2022 and may overtake a quarter of worldwide auto sales by 2035. Although driverless cars will need to overcome significant hurdles before their universal adoption,

they have the potential to provide consumers with increased safety, accessibility, and productivity all while decreasing wasted fuel, time, and energy.

One of the most popular propositions for self-driving vehicles is the possibility of increased road safety. Close to 90 percent of crashes are caused by avoidable mistakes made by drivers—excessive speed, disobedience of traffic rules or norms, and misjudgment of road conditions. Self-driving vehicles could eliminate human error in the driving process, potentially preventing an annual 37,000 deaths and 2.3 million injuries each year in the U.S. alone. Additionally, both the inner and outer

\$42
million

expected self-driving
vehicle market in 2025

composition of a self-driving vehicle will most likely appear very different from the vehicles of today. If the nature of accidents changes, the materials used to frame vehicles may no longer be steel and aluminum. A steering wheel and airbags may no longer be necessary, freeing up space for new and innovative design.

Another positive impact of the widespread adoption of self-driving vehicles could be an increase in the capacity of our nation's roadways. Throughput, or number of cars per hour on a roadway, is not the only possible improvement. An increase in throughput would require fewer and narrower lanes because of the accuracy and driving control of self-driving vehicles. Cars in communication with each other could safely follow each other at a much reduced distance, maintain and adjust speed more effectively, and even benefit from drafting other vehicles. Fewer crashes would result in a reduction in wear and tear of our nation's infrastructure. Increases in roadway capacity could bring more convenient travel that involves less wasted fuel and time.

Because fully automated self-driving vehicles would require virtually no assistance from a human driver, the automobile user base has the potential to expand widely. Young, disabled, and elderly people who would normally be physically unable to drive could achieve mobility without the assistance of others. If self-driving

vehicles could be programmed to adhere to traffic rules, fewer driving violations would be committed. Of course, the question then arises of what America's police departments would do without the \$6.3 trillion paid in speeding tickets every year.

As consumers know all too well, owning a car is expensive. The total cost of ownership today can be broken into seven different costs: fuel, purchase, interest, insurance, depreciation, maintenance, and sales tax. Most Americans families are paying this twice over – the U.S. Department of Transportation says that most households own more than one car. Yet cars tend to sit idle for hours in parking garages and driveways. Self-driving vehicles have the potential to make these hours useful to others, both within the family and the community. The very concept of vehicle ownership could evolve into a number of forms: private entities that rent per mile, car-sharing co-ops, and even publicly owned fleets.

Operating costs would also decrease in a world full of self-driving cars. As a result of fewer accidents and more efficient vehicle operation, car repairs and maintenance costs could go down. Safer vehicles might apply downward pressure on the price of insurance policies. If vehicles are smaller and more aerodynamic, perhaps they could support an increased baseline miles per gallon. Simply driving the speed limit and drafting other vehicles could result in fuel cost savings. This could be good news for both your wallet and the environment – if only ten percent of the cars on the road were self-driving, 102 million gallons (or 386 million liters) of gasoline would be spared.

Decreased travel costs in both time and money could have major implications for the American public. First, trips would require less effort and funding. Experts predict that the rise of self-driving vehicles could cause a 160 percent increase in travel. Just when you thought it couldn't get any better, imagine that your morning commute could be spent answering emails or grabbing an extra hour of sleep. If commuting time could become more productive or restful, professionals might be

more likely to move away from urban centers and create urban sprawl. On the other hand, over 9 billion people are predicted to live in urban areas in the next 25 years. Self-driving vehicles may be able to park themselves outside city limits cutting back on the need for urban street parking. A decreased demand for urban parking could allow existing parking spaces and garages to become more useful living spaces.

Alas, you will be driving your kids to school until the self-driving vehicle can overcome a number of challenges. If you have ever driven a car, you know that drivers today must make countless split-second decisions in order to drive safely in a rapidly changing environment. Drivers must recognize and classify objects, resolve conflicting messages, conduct trip planning, and complete the mechanics of driving on a real-time basis. In order to ever be considered safe enough for use, self-driving vehicles must meet and surpass this standard. Additionally, like all groundbreaking

technologies, the development of self-driving vehicles is expensive. At least in the beginning, the purchase price of a self-driving vehicle will likely reflect its various technological advancements. As the adaptation of self-driving cars expands, some people speculate that jobs such as traditional taxi drivers, car mechanics, parking attendants, and even bus drivers could be eliminated, or at the very least, dramatically diminished. Additionally, before consumers can even consider buying one of these vehicles, they must be proven to be secure from cyber-attacks. Finally, self-driving vehicles raise an entirely new category of liability issues. Lawmakers and automakers will have to collaborate to answer important questions related to the vehicles' liability.

Until self-driving vehicles can overcome these challenges, we are left as hopeful speculators, pondering the vast potential impact that they could have on our lives. A driverless future could be safer and more efficient than the world we now live in, but the question remains: how will consumers react to literally taking a backseat in their own vehicles? ◀

\$6.3
trillion
potential losses in
speeding-ticket revenue

Encapsulating the New Fountain of Youth

Olivia Ferguson

The Anti-Aging Movement

Are we obsessed with living longer? Many would say yes. Or, if not living longer, obsessed with fighting the symptoms of aging. The anti-aging market, described by Transparency Market Research as including anti-wrinkle products, hair color, hair restoration treatment, and various cosmetic procedures, has a projected value of \$191.7 billion by 2019 — a 7.8 percent growth rate from 2013. This industry is primarily comprised of short-term solutions to these symptoms. Wrinkles can be smoothed away with a little Botox, grey hair can be dyed, and even balding can be combatted. But these solutions address aging once the process has already begun. Aging is scary. It is inevitable. But what if you could postpone the symptoms and, in turn, promote longevity? This is what the anti-aging movement, a social movement encompassing physicians, patients, and other health professionals, hopes to achieve.

The Body as a Machine

One popular idea within this movement, spearheaded by Dr. Aubrey de Grey, is the concept that the human body is similar to a machine with parts that can be repaired and replaced indefinitely. The SENS Research Foundation, of which Dr. de Grey is co-founder and CEO, notes that 90 percent of deaths in the developed world are from causes that only rarely affect young adults, such as Alzheimer's, cardiovascular disease, and most forms of cancer. This observation, in turn, suggests the cure to aging is not to stop it, but to prevent the symptoms of aging that lead to death. In 2000, following years of research, Dr. de Grey came to the conclusion that "aging could be described as a reasonably small set of accumulating and eventually pathogenic molecular and cellular changes in our bodies, each of which

is potentially amenable to repair." The author and biomedical gerontologist believes the technology to repair the aging parts of the human body currently exists, but funding is lacking. Dr. de Grey also contends that we are less than 25 years away from attaining these regenerative medicines.

A New Little Blue Pill

This brings us to Basis, a small blue soft-gel tablet produced by Cambridge, Massachusetts-based Elysium Health. Leonard Guarante, renowned MIT-based biologist and co-founder of Elysium, has worked

toward the elongation of life his entire career. Previously involved with Sirtris Pharmaceuticals, a biotech startup that studied the anti-aging compound in red wine, the scientist feels hopeful about his current project.

Basis tablets come with a recommended dosage of two per day for the rest of your life. The pills contain Nicotinamide Riboside (NR) and Pterostilbene. Upon researching these ingredients (which I'll admit took me a few tries to pronounce correctly, much less spell correctly), results

indicate both are considered within the scientific community to have anti-aging properties and both are linked to reversing degenerative conditions. Though the potential uses of NR and Pterostilbene have only been discovered in the last few years, their potential is immense. However, to test the promise of anti-aging requires a small leap of faith. Unlike pharmaceuticals, nutraceuticals like Basis do not require approval from the U.S. Food and Drug Administration (FDA).

The Fine Print

A friendly warning label appears on the Basis container and website urging all to consult a physician before



taking the supplement. However, one could argue the majority of consumers bypass the warning label — as they do every “Terms & Conditions” form ever — figuring the product is safe enough to have made it into a commercial container. While the chemicals have been tested on worms and mice, the human trials are only just beginning. That’s the challenge of an anti-aging supplement; it literally takes a lifetime to prove. So far, Eric Marcotulli, co-founder and CEO of Elysium, suggests reactions have been positive. In a statement to Consumers’ Research, Marcotulli notes,

“The human data we have evaluated, which we are expanding into a larger and longer-term clinical study now, demonstrates the ability for the components of Basis to increase NAD+ levels. This alone is a reason to believe in Basis for consistent and prolonged use. Additionally, we have received unsolicited customer feedback related to higher levels of energy, greater cognitive function, and deeper sleep.”

With that, the company invites consumers to be its test subjects as well as a part of what could be “the next big thing.”

A Society Obsessed

As mentioned, there is no reliable evidence that any current anti-aging medicines or treatments do what they claim. S. Jay Olshansky, longevity specialist and professor at the University of Illinois School of Public Health in Chicago, says, “It is easy to get seduced into the claim that there is something called anti-aging medicine... Exercise is about the only equivalent of a fountain of youth that exists today. It improves skin elasticity, muscle tone, bone density — and you can do it for free, or pretty much free.”

As science brings us closer and closer to making the symptoms of aging a thing of the past,” the next question to ask is not “can we” but, rather, “should we?” In short, what happens when age-associated illness is defeated? In the long run, is it even a good

idea? Critics of the movement cite overpopulation, along with its many associated troubles, as a concern. While we are not there quite yet, leaders of the anti-aging movement, including Dr. de Grey, are not worried. The human race will adjust. ◀

Emerging *from the* GM Ignition Switch Recall

Millan Bederu & Kyle Burgess

It has been nearly two years since initial reports of the General Motors Company (GM) ignition switch recall made it into the public eye. What followed was a difficult trek through congressional hearings, federal investigations, and civil court cases surrounded by high publicity – not to mention a growing number of attributed fatalities. The question of responsibility was at the pinnacle of all major liability cases against GM. Was New GM, the company formed following the 2009 bankruptcy filing, liable for the actions of Old GM (General Motors Corporation)? The company, of course, argued it was not. However, beyond the scope of the company itself, the GM recall significantly influenced the automobile industry as a whole, serving as a lesson on the importance of immediate action and transparency by automakers and their regulators when consumer safety is on the line.

Ignition Switch Recall in Review

On February 14, 2014, newly appointed CEO of General Motors Company Mary Barra enacted a recall of GM's ignition switch. However, news traveled quickly that GM had been aware of the faulty ignition switch for a decade yet did nothing to stem the use of the part. Reports highlighting the ignition switch's sensitivity to heavy key chains and jostling, causing the ignition to switch to the off position, circulated within the company as early as 2003. Harm resulting from sudden ignition shut-off was originally calculated to be minimal, but later reports showed that if cars were to suddenly switch off, causing a collision, air bags could also be deactivated and would not deploy without power. It was precisely this danger that resulted in numerous fatalities.

Originally only owing to 13 deaths, the number of fatalities GM claimed responsibility for has risen to 124 since the recall. GM has also acknowledged its role in 17 serious injuries (i.e. amputation, paraplegia, quadriplegia, brain damage, and severe burns), and 258 hospitalizations and outpatient treatments. However, GM has declined to recognize more than 4,000 other claims of death, injury, or other loss as a result of the faulty ignition and currently has no legal

requirement to do so for claims related to incidents occurring prior to the 2009 restructuring.

Since the 2014 recall announcement, GM has undergone investigation by multiple federal agencies and Barra has been called to testify in front of Congress on four occasions. In a settlement announced in September, GM agreed to pay \$900 million to the U.S. Department of Justice (DOJ) for its failure to disclose the ignition switch safety defect, an amount that outweighed GM's set-aside fund for victims and their families by \$300 million.

The recall tragedy began well before the February 2014 announcement, and the consequences will likely continue to play out for some time to come. Though the Congressional hearings on the ignition recall have come to an end and the DOJ settled and has ruled out criminal charges, legal battles in civil courts are ongoing. In the spring, a federal court ruling shielded GM from over 100 civil cases of injury or loss occurring prior to the 2009 restructuring; however, instances where people were injured post-2009 due to the faulty ignition switch may still be able claim damages against New GM. As it stands, the recall includes 2.6 million vehicles worldwide.

The lawsuits against GM follow the company's settlement with the family of a Georgia woman killed in an accident resulting from the faulty ignition switch. The settlement led to the creation of GM's compensation fund for the victims and the families of victims who agree not to file charges against the company. GM has confirmed that the ignition malfunction has resulted in hundreds of deaths, serious injuries, and hospitalizations since 2009 and has given 295 offers of compensation from the established fund. Initially GM said it expected to spend \$400 million on claims, but that amount rose to over \$600 million during the summer. However, by fall, those who qualify for the fund have only received \$93 million in compensation – just under ten percent of what the DOJ settled for.

Numerous individual GM owners, as well as the State of Arizona, launched cases against the company claiming

that GM misled customers concerning the resale value of their vehicles. Essentially, owners of the effected GM vehicles claim the resale price, and therefore value, of their cars has been negatively impacted by the GM ignition recall. Defendants of GM argued the company's 2009 bankruptcy absolves the current permutation of the company from damages inflicted by the earlier pre-bankruptcy company. Judge Robert Gerber, who presides over the U.S. Bankruptcy Court for the Southern District of New York, ruled that the New GM is not liable for the mishandling of the Old GM.

Claimants may still be able to secure a victory, however, if they are able to show that New GM continued the poor handling of the malfunctioning ignition switch. In other words, if New GM knew about the problem and continued to cover it up instead of issuing an immediate recall, Judge Gerber's ruling may not apply to cases brought on these grounds. This would have been the basis for potential criminal charges against GM and possibly the attorneys who advised GM in this matter as well, but the DOJ did not seem to think it could build a strong enough case for criminal charges.

Failure of the NHTSA

The GM ignition recall resulted in an initial congressional hearing in April 2014 and an investigation follow-up in June of 2014. The congressional hearing, entitled "GM Ignition Switch Recall: Why Did It Take So Long?" was under the authority of the Subcommittee on Oversight and Investigations. Committee members put questions to Barra and implicated both General Motors and the National Highway Transport Safety Administration (NHTSA) in failure to recognize or report the issue in a timely manner. The Oversight Subcommittee did a review of the NHTSA's handling of the situation and in a majority memorandum from September of 2014 stated that the NHTSA had "ample information" in 2007 about the ignition defect and coinciding air bag deployment failure. The Committee decided that the NHTSA failed to properly regulate GM's handling of the situation.

The Committee's decision has increased pressure on and from regulatory bodies, which has pushed carmakers to issue recalls more readily – for now. In January, NHTSA administrator Mark R. Rosekind said that 2015 would likely see higher rates of recall than even the record highs of 2014; however, that does not appear to be the case, given that by September, 2015

recall numbers were at half the level of recalls for the whole of 2014.

To many, the failure of the NHTSA to catch and report the deadly defect suggests a failure of the agency itself, inducing Congress to consider an overhaul of the Administration. In early November, the House voted to slash the Senate-proposed budget increases for the NHTSA by roughly \$15 million per year, while keeping in place the expectation of a 40 percent increase in vehicle safety by 2021. However, the same week the House voted to cut the proposed budget increase, the NHTSA levied a \$70 million fine against Takata for its handling of airbag defects.

GM Rebound & Recovery

To date, the ignition switch recall has cost GM approximately \$4.1 billion, but has done little to tarnish the name of the auto-giant. GM sales continue to grow. The company's recovery was likely supported by the record-low oil prices experienced by consumers for the 2014 – 2015 winter. However, despite little effect to sales, company stocks were not unaffected by the recall. GM stocks dipped from July through October 2014, hitting lows that the company had not seen since April 2013. Though GM's stock price has picked up since last October, it has not yet rebounded to its post-crisis peak in December 2013. However, analysts expect there will be no long-term effect on the value of the company.

In August, GM recalled over 70,000 2010 Chevrolet Cobalts in the U.S. and Canada due to improper wiring that may prevent driver's side air bags from deploying upon impact. This news comes on the heels of GM's overseas recall of new Chevrolet Malibus due to airbag defects in May. GM was also involved in the massive Takata airbag recall earlier this year, resulting from defects responsible for the death of six passengers in the United States. These recalls on newer model vehicles demonstrate GM's faster call to action than what came to light in last year's faulty ignition switch fiasco. However, with sales left largely unaffected, civil legal responsibility partly deflected on a technicality, and criminal charges off the table, have auto manufacturers truly learned their lesson on prioritizing vehicle safety over corporate gains? ◀

Global Integration Calls for Open Collaboration

Olivia Ferguson

Looopholes & Patent Trolls
In its Winter 2014 issue, Consumers' Research discussed how the intellectual property (IP) protection system is designed to protect both consumers and innovators alike. While the system boasts a number of successes within the realm of consumer protection, many complain the current system is weak and littered with loopholes that allow patent trolls to reap undeserved rewards. Apple Inc. for example, made headlines in the spring for being ordered by a federal court in Texas to concede \$532.9 million to Smartflash LLC, a small Texas-based licensing company. Smartflash has filed lawsuits against Samsung Electronics Co., HTC Corp., Google Inc., and has hit Apple with a second lawsuit following its win. In September, the Texas federal court granted Apple a stay on a damages retrial until Apple's appeal of the jury's determination of liability is resolved. Smartflash owner, Patrick Racz, holds fast to his assertions of IP infringement, pointing to the dates he filed for the patents he invented.

Smartflash contends that its patented software is used as an integral part of all digital-downloading, and therefore covers all music and app downloads. Because the software is so fundamental, many major digital-downloading companies have been accused of using the patented software. Apple argues that, while their software does incorporate some of the patented technology, because the software is so inherent, Apple likely came to the development of it on its own. Racz counters this, stating that his senior research and development director left to work for Apple, an untimely and questionable event that ultimately caused Racz considerable financial damages. While companies could (and do) fight back and forth about the origins of their software, the case probes a larger question. As technology becomes more and more integrated (and therefore dependent), how will intellectual property laws adjust to accommodate intellectual overlap?

Within Technology, is Sharing Caring?

When Elon Musk announced last summer that Tesla, Inc. would release its patents to the public, many were

shocked. Across numerous industries, it is widely accepted that the value of one's work is determined by its rarity. For example, within the pharmaceutical industry, a drug developed by just one company is worth more than if it were produced by a range of competing companies. Similarly, the news that Tesla technology would no longer be a rarity caused many to assert Musk was limiting the future value of his vehicles. But Musk has other plans. Seeing beyond the unspoken rule of never showing your cards (or cars), Musk noted the greater potential for technology development with industry collaboration. He states,

“At Tesla, however, we felt compelled to create patents out of concern that the big car companies would copy our technology and then use their massive manufacturing, sales and marketing power to overwhelm Tesla... Technology leadership is not defined by patents, which history has repeatedly shown to be small protection indeed against a determined competitor, but rather by the ability of a company to attract and motivate the world's most talented engineers.”

Musk is not the only tech leader to acknowledge the progress possible from industry collaboration. Today our society is functioning more and more on technology systems. Not only can we now monitor our homes remotely, but applications, software, and systems within the home (including refrigerators) can be integrated and controlled from a single remote device. As we become more and more dependent on these integrated systems, a common platform is needed to ensure interoperability and frictionless use. In other words, unless these new technologies are easier to use than traditional tools (think, Nest versus the standard thermostat) then there is little incentive for consumers to adopt new ones.

Take Apple Pay for example. Announced in the fall of 2014 the mobile payment system was met with excitement, boasting a new way to make transactions quicker and more secure. All consumer would have to do is wave their iPhone screen across a scanner

at checkout and their account would be charged for the purchase. But Apple Pay hit a bump in the road when CVS Health Corp. and Rite Aid Corp. disabled the system due to the companies' participation in a competing mobile payment service called the Merchant Customer Exchange Program (MCX). Aptly put by Ryan Egan, writer for TechSmash:

“If a user has to use Apple Pay at one retailer, Google Wallet at the next, and Merchant Customer Exchange at another; that person is likely to just pull out their debit card or pay with cash. Without an industry leader to push a unified eco-system, the Internet of Things will continue to be a poor consumer experience.”

It is this unified experience that leading technology companies are pursuing. Cisco Systems Inc., Intel Corp. and Verizon Communications Inc. partnered in Fall 2014 in an attempt to create a unified platform on which all IoT systems can function. However, many argue there is no need for such a platform. Rather, some industry experts argue a network of independent, but compatible, systems of software is a more attainable goal than one overriding system. In March, Panasonic Corp. released the patents for its Internet of Things (IoT) framework and corresponding software, OpenDOF, in an attempt to foster more collaboration among IoT industry developers. By allowing other companies to utilize their patents for product development, Panasonic brings the potential for a unified IoT system much closer. While it is currently unclear which approach to the IoT system will prevail, both require the cooperation of innovators and access to independent technology patents.

Protecting a Shared Commodity

This is not a new idea. In fact, there is an entire movement dedicated to such a concept. The open patent movement (often referred to as the open source movement) seeks to build a portfolio of creations that can be freely distributed and built upon. The Free Software Foundation founded in 1985, is just one of many groups dedicated to the innovation that can arise from collaboration among experts. The group “defends and promotes computer users’ right to use, study, copy, modify, and redistribute computer programs.” A key point to the mission of these groups is the belief that as society becomes more and more dependent on computers, the software used to shape our lives should be accessible to all. However, with this philosophy comes the need for companies to be protected from lawsuits born out of the new software developments. Many believe that a company that chooses to release its patents in the name of progress and goodwill should be permitted to use the products created from the original technology without facing

penalties. This notion has resulted in the formation of open software networks, or Open Innovation Communities (OICs), for which membership hinges on the mutual agreement to share.

According to Jason Schultz and Jennifer Urban’s paper, published in the Harvard Journal of Law and Technology, “Protecting Open Innovation: The Defensive Patent License as a New Approach to Patent Threats, Transaction Costs, and Tactical Disarmament,” OICs opt out of the traditional patent system because patents are expensive, patents oppose the philosophical values of OICs, and there is little guarantee patents will prevent bad actors from obtaining them and using them offensively. Defensive patents, on the other hand, are used primarily to defend a company against patent infringement lawsuits, allowing the holder to countersue when a competitor sues for infringement or even avoid patent lawsuits altogether.

Google, for example, states on its corporate website that while the company, “is committed to promoting innovation to further the overall growth and advancement of information technology and believes Free or Open Source Software is a very important tool for fostering innovation,” it goes on to note,

“Accordingly, Google reserves the right to terminate the Pledge, to the extent Google deems necessary to protect itself, its affiliates, or its products and services (“Defensive Termination”) with respect to any Pledge Recipient (or affiliate) who files a lawsuit or other legal proceeding for patent infringement or who has a direct financial interest in such lawsuit or other legal proceeding (an “Asserting Party”) against Google or any entity controlled by Google or against any third party based in whole or in part on any product or service developed by or on behalf of Google or any entity controlled by Google.”

In other words, a person who uses and in turn develops software from the original Google technology cannot seek patent infringement and/or financial compensation from Google.

Patent Reform

As Thomas Jefferson said, “Nothing is troublesome that we do willingly.” In essence, intellectual property laws exist to protect the consumer and the creator. But these laws are changing. As many call for the reform of outdated IP laws, questions arise regarding how the growth of technology and the reach of Internet of Things influence these matters. Moving forward, it is crucial to consider the potential of innovative collaboration, as well as the effects of new legislation on consumers and creators. ◀

New Immunotherapies *Hope to Transform Cancer Treatment... If We Can Afford Them*

Alec Engber

The way we treat cancer is changing. Traditional cancer therapies most often involve surgery, radiation, and chemotherapy – surgery to cut out the cancer, radiation to bombard and destroy it with high-energy waves or particles, and chemotherapy to kill it with strong medications. These treatments may cause relatively severe side effects, damage healthy cells, or even result in death. Enter the immune checkpoint inhibitor, a new cancer drug with the potential to improve the way we treat cancer by orders of magnitude.

The new medications use patients' own immune systems to combat cancer cells in the body. There are currently three types of immune checkpoint inhibitors on the market: CTLA-4 inhibitors, PD-1 inhibitors, and related PD-L1 inhibitors. All three target various proteins related to the function of T-cells, which are naturally-occurring white blood cells with proteins on their surface to help the body detect and destroy foreign threats.

Exactly how cancerous cells manage to evade the body's immune defenses has long baffled researchers. However, a growing body of evidence suggests certain proteins on the surface of cancer cells attach to T-cells and effectively deactivate the cells by preventing them from triggering the appropriate immune response. Without the warning signal from these T-cells, the body is unaware of the cancer's presence and neglects to unleash the antibodies responsible for eliminating the intruder.

The different types of immune checkpoint inhibitors work in distinct, but related, ways with varying degrees of success. CTLA-4 inhibitors, like Bristol-Myers Squibb's Yervoy, "block" the CTLA-4 receptor on the surface of T-cells, which is used to regulate the body's immune response. This allows the T-cells to carry on killing cancer cells unimpeded by the body's natural regulatory mechanism. While this has proven effective in reducing the recurrence of late-stage melanoma by about 25 percent, other common cancers, such as lung and pancreatic cancer, have not displayed the same level of response to CTLA-4 treatment.

PD-1 and PD-L1 inhibitors function much like CTLA-4 inhibitors, but have proven to be more effective at treating a wider variety of cancers. Rather than removing the immune system's ability to regulate the function of certain T-cells, these new checkpoint inhibitors disable proteins that more directly obstruct the ability of T-cells to recognize and destroy cancerous cells throughout the body. PD-1 inhibitors block a protein on the T-cell, called "programmed death-1," to which cancer cells attach their corresponding "ligand" (imagine that the cancer ligand is the "key" to the T-cell's "lock" receptor), thereby preventing the T-cell from performing its function and concealing the presence of the cancer cell from the immune system. PD-L1 inhibitors target the ligand on the cancer cell itself, blocking it from attaching to and disabling T-cells.

PD-1 inhibitors like Merck & Co.'s Keytruda and Bristol-Myers Squibb's Opdivo, and PD-L1 inhibitors like the one under development by AstraZeneca Plc, have demonstrated effectiveness in treating melanoma, lung cancer, lymphoma, bladder cancer, and other forms of the disease. Swiss drug maker Roche Holding AG has also said that it hopes to have 11 different immune checkpoint inhibitors in the clinical trial stages by the end of 2015. In one such trial, those receiving PD-1 immunotherapy for advanced melanoma had a survival rate of 73 percent after one year, compared to a survival rate of 42 percent for traditional chemotherapy. PD-1 and PD-L1 immunotherapies produce a response among 25 to 40 percent of patients, which is significantly greater than the ten percent or less of patients who benefitted from previous immunotherapies. Furthermore, chemotherapy is relatively untargeted and has a notoriously high potential for negative side effects, including hair loss and severe nausea. By contrast, 90 percent of patients receiving targeted checkpoint inhibitors for treatment do not seem to experience severe side effects.

One reason this new treatment has inspired hope among oncologists is that, unlike melanoma, lung cancer typically does not respond to traditional immunotherapies. The ability of these new PD-1 and PD-L1 immune checkpoint inhibitors to combat lung

cancer is encouraging, given that lung cancer is the leading cause of cancer-related death in the world. In March, the U.S. Food and Drug Administration (FDA) approved Opdivo to treat non-small-cell lung cancer in addition to its previously approved use as a treatment for melanoma. The FDA also granted Keytruda accelerated approval for the treatment of melanoma in September 2014 and subsequently designation as a “Breakthrough Therapy” for non-small cell lung cancer in October. This designation allowed pharmaceutical companies to expedite the clinical trial and regulatory approval process in order to get promising new drugs on the market sooner. The FDA recently announced that Keytruda has been “approved for use with a companion diagnostic, the PD-L1 IHC 22C3 pharmDx test, the first test designed to detect PD-L1 expression in non-small cell lung tumors.”

“Having a potential new way to keep melanoma at bay is a major advance for patients who live under the constant fear of recurrence after surgery. It’s also incredibly exciting that we’re extending the benefits of immunotherapy beyond melanoma, to diseases like cervical cancer where patients urgently need better options,” said Dr. Steven O’Day, of the American Society for Clinical Oncology (ASCO) and professor of medicine at the University of Southern California, Keck School of Medicine. Moreover, according to Dr. Rolf Stahel, president of the European Society for Medical Oncology, new immune checkpoint inhibitors may be especially useful in treating kidney and lung cancers, which grow slowly and are therefore difficult to treat by traditional means.

“PD-1/PD-L1 inhibitors look important across a pretty wide swathe of cancers. What got people excited was a lesser [compared with melanoma] but still significant response rate in non-small-cell lung cancer (NSCLC), as well as in bladder, and head and neck cancers,” said Dr. Louis Weiner, immunotherapy expert and gastrointestinal oncologist at Georgetown University.

Combining these drugs with other existing treatments has proven to be far more effective than immunotherapy alone. Still, they have only triggered a response in some patients and the response time is considerably slower than some other targeted drugs, offering potential insight into how future cancer treatments may employ them.

Doctors, insurance companies, and consumers view the enormous price of immune checkpoint inhibitor drugs as the greatest hurdle to their widespread adoption. In the last decade, the cost of treating cancer has increased twofold to roughly \$10,000 per month, even before these pricey new drugs hit the market. Merck & Co. estimated that a combination treatment incorporating Keytruda could push costs even higher, to \$150,000, or more, annually. Pharmaceutical companies argue that the high price tag is justified, given the amount of money spent developing cancer drugs, which is estimated to comprise 23 percent of the \$70 billion spent on pharmaceutical research annually. Forecasts predict that sales of these and similar immunotherapies currently under development by AstraZeneca Plc and Roche Holding AG may total \$30 billion annually once the treatments are fully implemented.

While this would indeed be a handsome return on the corporations’ costly investments in cancer research, it has concerned insurance companies and doctors alike. America’s Health Insurance Plans, a trade group that represents U.S. health insurers, expressed alarm at the “astronomical price tags” the impending wave of new cancer drugs will carry. Meanwhile, a 2014 report by the ASCO predicted a 40 percent increase in the cost of cancer treatment in the United States by 2020, to \$175 billion. This could prove prohibitively expensive for American consumers, who already have little option but to pay for high-priced cancer treatments out of pocket. A report released by the consultancy IMS Health argued that, “Financial toxicity, or more generally the financial burden of disease, is a side effect just as potent as fatigue or nausea in patients.”

Combined with physician shortages and growing demand for cancer treatment, the immense cost of immunotherapeutic drugs is “a serious threat to the nation’s cancer care system which already is straining to keep up with the needs of an aging population. Without immediate efforts to address these threats to oncology, we’re at real risk of failing tomorrow’s cancer patients,” said ASCO president Clifford A. Hudis. While immune checkpoint inhibitors have the potential to greatly improve cancer treatment in the U.S., many patients may be forced to choose between their physical wellbeing and their financial wellbeing if treatment does not become more affordable. ◀

Approval Purgatory: 23andMe and FDA Restrictions on Consumer Agency

Editorial

Kyle Burgess

Over the summer America lost Dr. Frances Oldham Kelsey, a brilliant and vigilant public servant who, despite adversity and pressure, refused to approve a drug she believed to be harmful to consumers. In the early 1960s, thalidomide was routinely prescribed to pregnant women in Europe to curb morning sickness; however, Dr. Kelsey noticed a potential link between thalidomide use and severe nervous system side effects in infants. She successfully fought to keep the drug off the U.S. market and is celebrated for sparing countless American infants from suffering serious birth defects. She is also lauded for triggering legislation requiring that pharmaceutical products be proven safe and effective before receiving U.S. Food and Drug Administration (FDA) authorization to go to market.

Dr. Kelsey retired from the FDA in 2005 at the age of 90. In her 45-year tenure, the FDA made many improvements to the approval process for pharmaceuticals and medical devices. For example, committees and panels of experts comprised of physicians, statisticians, chemists, pharmacologists, and other scientists now review these products and make recommendations to the FDA, as opposed to the seven full-time and four part-time physicians reviewing drugs in Dr. Kelsey's early days at the FDA.

Dr. Kelsey's contributions to the FDA were intended to ensure that medicines and medical devices did not harm consumers more than they helped consumers. In recent years, however, the FDA has blocked the marketing of an affordable tool that could have vast potential for improving the quality of healthcare, which has not been demonstrated to harm consumers. That tool? The personal genome service (PGS) offered by 23andMe.

In 2003, an international team of scientists fully sequenced the human genome for the first time in history. By 2010, roughly 30 companies were selling direct-to-consumer (DTC) genetic and genomic tests, some offering PGS – interpretations of genetic predisposition toward developing, having or carrying a number of diseases and medical conditions, such as diabetes or breast cancer. Most of these companies

discontinued the sale of their health-related tests due to increased regulation. With the FDA approval of one of its DTC genetic tests granted in February as well as permission granted to allow carrier status results again in October, as it appears that the cavalier approach of 23andMe will likely succeed in the quest to provide PGS to consumers – shifting the question from *will*, to *when will* 23andMe's full PGS be approved?

Based on a recent letter from the FDA to 23andMe that when might be before year's end. It also might not. It took one year for 23andMe's first test to obtain FDA approval – three, if you start the clock at 23andMe's first premarket notification submission. No additional DTC genetic tests have obtained FDA authorization in the nine months since the first approval and carrier status does not impact consumers' personal health. This interminable wait is harmful to consumers who could be armed with accessible information about their potential health risks and agency to act on this information. Those who enjoy 23andMe's full product offering of health-related results may use their results to have informed conversations with medical professionals, bettering their quality of healthcare. While stuck in FDA approval purgatory, 23andMe's current offering is limited, preventing newer customers from accessing their personal health information and seeking medical guidance regarding potential health risks.

According to the FDA's November 2013 warning letter, 23andMe failed to get market approval, which was necessary to assure its tests were accurate, reliable, and clinically meaningful. The FDA was particularly concerned with consumer reactions to results, especially a false positive, indicating a BRCA mutation, contending that consumers may undergo surgery to prevent breast and ovarian cancer without consulting a physician. However, a 2013 study published in *PeerJ*, demonstrated that all surveyed women identified as having a BRCA mutation consulted a doctor after receiving results and those who opted for surgery consulted multiple doctors. The study also showed that those identified as having the mutation were likely to share test results with family members, prompting at risk people to seek testing.

This study did not investigate the risk to consumers who receive a “false negative” for the BRCA mutation and the FDA expressed concern that consumers will forgo further testing if they receive a “false negative” for these types of mutations. However, the FDA’s role is not to limit consumer choice because it thinks consumers cannot make good choices for themselves. For its breast and ovarian cancer results, 23andMe makes it clear that the result only covers a specific subset of women and one of many different mutations associated with breast and ovarian cancer risk. The FDA’s responsibility here is to protect consumers from harm, not from themselves.

The FDA also stated that it has a “longstanding policy that providing what looks like disease diagnoses made 23andMe’s service a medical device. That means it’s subject to explicit FDA approval.” 23andMe does not claim to provide diseases diagnosis; rather, it offers an interpretation of one’s likelihood to have a genetic predisposition toward developing a number of diseases and medical conditions based on specific studies. It also provides information on the presence of genetic variants associated with having or carrying certain diseases. 23andMe’s user guidance on the interpretation of this information is as follows:

“These reports show your results for specific genetic variants that can cause certain health conditions. Many of these conditions are recessive, meaning that they only occur when you have two variants for that condition, one inherited from each parent. If you have inherited just one variant, you are said to be a “carrier”. Carriers usually do not have the condition, but can pass the variant on to their children. Note that these reports cover only a subset of possible variants that may be linked to a condition. It is thus possible to have other variants not covered by these reports.”

While the FDA has so far limited 23andMe’s test

offerings, it is allowing firms such as Counsyl and Pathway Genomics to offer genetic tests through doctors without FDA approval. The costs of such tests through doctor visits can be prohibitively expensive for many consumers. The Health Insurance Portability and Accountability Act (HIPAA) establishes patients’ right to control their medical information. FDA restrictions on PGS impose on consumers’ right to agency over their own medical records by pricing them out of permissible genetic test options and precluding them from accessing affordable DTC genetic test options.

When Dr. Kelsey set out to improve the FDA’s approval process, her primary objective was to ensure that the benefits provided by drugs and medical devices outweighed their potential risks. At the moment, that does not appear to be what’s happening. PGS data should undergo the full rigor of scientific review, so long as there is compelling evidence that it may be harmful. To date, 23andMe has demonstrated that the benefits of PGS are numerous and the risks are unsubstantiated. Technology is developing rapidly and regulators are struggling to keep pace; however, consumer agency should not be limited by “the law of instrument,” shoehorning new tools into outdated paradigms. ◀

TSA Pre-Check Makes Screening Faster, *But Maybe Not Safer*

Alec Engber

The Transportation Security Administration (TSA) launched its “PreCheck” program in 2011 to allow certain frequent travelers to pass through airport security screening checkpoints faster and without the hassle of going through the normal procedure – placing laptops, liquids, and shoes in bins for x-ray and passing through a full body scanner. In 2013, the TSA expanded the program to allow anybody to apply for PreCheck and, if approved, pass through the expedited security lanes with their shoes on and their personal belongings packed away.

To apply, one need only provide some basic personal information (address, city of birth, criminal history, and so on), get fingerprinted at an enrollment center, and pay an \$85 fee. Once the application is approved, enrollees are provided with a Known Traveler Number (KTN), which can be entered when purchasing a flight through one of the 11 participating major airlines. Airlines have a limit on the number of passengers per flight that can take advantage of PreCheck, so enrollees are not necessarily granted the privilege each time they travel.

In March 2015, acting TSA administrator Melvin Carraway celebrated the growth of PreCheck enrollment to one million people saying, “This milestone is a testament to the outstanding collaborative work between TSA, airports, airlines and most importantly, the travelling public. With more than 330 application centers nationwide, it is easier than ever to apply for expedited screening.”

A study conducted by Purdue University in cooperation with the Cincinnati/Northern Kentucky International Airport (CVG) examined the impact of the PreCheck program on the speed at which passengers move through security from November through December of 2014. The study found that from 2011 to 2014, the median wait time for standard screening at the airport was reduced from 13 minutes to nine minutes, while the median wait time for PreCheck passengers represented an 11 minute reduction over the standard wait time in 2011 (before PreCheck was implemented). During the two-month research period, 55 percent of the 400,000 total travelers took advantage of the expedited screening – a very high rate compared to

many major airports. While these figures suggest an improvement in wait time for passengers thanks to the TSA PreCheck program, analysts suggest that the terminal reconfiguration undertaken at CVG during the same period may have contributed to the reduced wait time as well.

The rapid growth of the PreCheck program has not come without its fair share of controversy. Frequent air travelers have likely noticed that the PreCheck fast lanes are often sparsely populated or even empty during busy times, despite backups in the lines for standard screenings. This is in part due to the sheer volume of air travel in the United States, which saw 815.3 million passengers board flights traveling into or within the country in 2012. The one million PreCheck enrollees in 2015 thus represent less than half the average of 2.2 million passengers flying in the U.S. on a daily basis. The TSA has said that it hopes to enroll half of all travelers in the United States in the PreCheck program over the next several years. Without achieving significant progress toward that goal, those who are not “known travelers” will likely see little relief from the long lines and cumbersome security process for which the TSA is infamous.

In addition to increasing enrollment, the Administration has been evaluating various other methods designed to increase expediency without decreasing security. One such measure, called “managed inclusion,” allows TSA officers to randomly select passengers, whom they believe pose a minimal security threat, to forego the long lines and instead enjoy a free ride through the PreCheck screening checkpoint despite not being enrolled in the program. In theory, the “random” nature of this policy should largely mitigate the reduced level of security it produces. If unenrolled passengers cannot count on being allowed through the PreCheck line, it is unlikely they will be more inclined to bring prohibited items through security as a result of this measure.

This policy has been called into question following the March release of a report by the U.S. Department of Homeland Security (DHS), which found that a felon, convicted of explosives-related charges stemming from her involvement in a domestic terrorist organization,

was permitted to use the PreCheck lane after a TSA officer deemed her to be “low-risk.” The felon in question was identified as a former member of the leftist revolutionary group called the United Federated Forces of the Symbionese Liberation Army (SLA), which was responsible for a series of bombings, kidnapping, robberies, as well as a few murders in the early 1970s. The issue came to light after another TSA officer at the Minneapolis-St. Paul International Airport recognized the woman and alerted a supervisor, who nonetheless allowed her to pass through the expedited screening checkpoint. In response, a bipartisan group of House representatives introduced legislation to prohibit the TSA from allowing passengers to use the expedited screening checkpoints if they do not possess a KTN.

This case illustrates the central conundrum facing TSA officials. Meticulously screening every passenger alike is both inefficient and unnecessary for the overwhelming majority of travelers, but distinguishing those travelers who pose a potential security threat from those who do not is a nearly impossible task without such time-consuming procedures. Even with the full screening process in place, a recent study by the DHS found that TSA agents had failed to detect dangerous items carried through security by undercover agents 95 percent of the time over the course of 70 separate tests. Additionally, there is no guarantee that someone who has passed a background check will not attempt to carry out a terrorist attack once approved for the more relaxed screening process.

In 2007, the TSA sought to address this problem with the introduction of a program known as Screening of Passengers by Observation Techniques (SPOT). Under SPOT, the TSA trains certain employees, called behavioral detection officers, to observe passengers during the screening process and interact with them to determine whether they may potentially pose a threat based on their behavior. However, the program’s success is disputed and the methods employed to differentiate high-risk passengers from low-risk passengers have been criticized as subjective, stereotyping, and ineffective. Furthermore, a 2013

report by the U.S. Government Accountability Office found that the ability of a person to “accurately identify deceptive behavior based on behavioral indicators is the same as or slightly better than chance.” A separate study released the same year by the DHS concluded that the TSA had not evaluated the efficacy of the SPOT program, and therefore, “cannot ensure that passengers at United States airports are screened objectively, show that the program is cost-effective, or reasonably justify the program’s expansion.” Despite this, the TSA has spent over a billion dollars to expand the number of behavioral detection officers trained and deployed throughout the country’s airports by thousands.

The SPOT program aside, TSA PreCheck appears to be an effective means to reduce the time-consuming nature of airport security checkpoints in the United States. The amount of time it takes to go through security should be reduced even further as more travelers enroll over the coming years. However, this also raises a troubling issue with regard to consumer privacy. If PreCheck enrollment becomes the norm, then most travelers will effectively be forfeiting the privacy and security of personal information in exchange for bypassing the slow and invasive general screening process at airports. It is also undetermined whether such a program even improves traveler safety, calling into question whether the TSA PreCheck program warrants the anticipated increased enrollment. ◀

Consumer Protection is Worth an Extra Second at the Register

Editorial

Joe Colangelo

The payment card industry has some explaining to do.

According to an Aug. 30, 2013, joint public filing by Visa and MasterCard, “requiring the use of a personal identification number (PIN) rather than permitting signature as a means of customer authentication for transactions at Point of Sale is a proven method of reducing card fraud.” Unfortunately, for American consumers, that was from their submission to the Australian Competition and Consumer Commission. Here in the United States the companies have chosen to implement signature authentication only, a standard that by their own admission (in the same filing) is less secure.

Recently, millions of Americans have been transitioning to using a new type of credit card with an embedded chip that gets “dipped” into the credit card machine, joining their counterparts in Europe, Canada and Australia, whose citizens have been “dipping” for years. During the past few months, over 500 million of these cards have been mailed to American consumers.

My first experience with this technology came when I checked out at Target over Labor Day weekend. Like other retailers around the country, Target was starting to prepare customers for the transition to these “dip” cards, known in the payments industry as the Europay/Mastercard/Visa standard, or EMV. Quite simply, EMV technology is a big improvement over the current magnetic strip, which hasn’t changed much since its widespread introduction 35 years ago. While EMV won’t stop fraud, it makes it much harder to exploit someone’s stolen credit card information.

This is a positive development for consumers and businesses alike, and it is especially positive for Target, which suffered a high-profile data breach in 2013 that exposed the information of 40 million credit and debit cards. In August, Target agreed to pay up to \$67 million to financial institutions affected by the theft. As banks send customers new credit and debit cards, retailers are updating their payment terminals to accept them.

It’s good news for consumers, too. Since Oct. 1, if fraud occurs at the point of sale and a vendor hasn’t made the switch to EMV technology, that vendor can be held 100% liable the losses.

There’s just one problem.

In updating credit cards with EMV technology, Visa and MasterCard have neglected an important element of what makes EMV so successful elsewhere. Virtually



every other country in the world that has transitioned to EMV has paired it with PIN verification. In the U.S., card companies have chosen signature verification. This is a far less secure method of authentication that will leave consumers vulnerable and will undermine EMV's effectiveness.

The danger in choosing signature over PIN is twofold. First, for transactions where a machine has problems reading a chip, the equipment will automatically default and accept a magnetic stripe. When only signature verification is employed, this creates a simple workaround for fraudulent transactions in the event of a breach. Second, when – not if – hackers find a way to counterfeit EMV chips we'll be right back in the same vulnerable position we were in before.

In 2012, the U.S. accounted for 47.3% of global payment card fraud, but only 23.5% of global payment card volume. Last year, data breaches like those at Target and Nordstrom's cost retailers a combined \$32 billion. Consumers paid the price in the end. Fraud leads to higher credit card fees, which translates into more expensive goods and fewer payment options. It also undermines consumer confidence at a time when we need more market engagement, not less.

EMV technology is no silver bullet against fraud. The failure to employ a more secure verification method is irresponsible in an era of organized crime and cyber warfare, at a time when the Social Security numbers of 21 million people can be stolen from the U.S. Office of Personnel Management and (presumably) bought and sold over the Internet. The need for PIN verification is clear.

The Federal Reserve Bank of Atlanta has said chip-and-PIN verification is seven times more secure than chip-and-signature. The payment networks should be embracing this technology like they have done in Canada, Australia, and all across Europe.

The U.S. is one of the last industrialized nations to adopt EMV technology. Now that we have, domestic consumers deserve the same protections and data security standards enjoyed by the rest of the world, and a signature just doesn't cut it. The trade-off from chip-and-PIN verification is worth an extra second at the register — especially if it means more protections and lower prices. ◀

Bitcoin and the Collaboration Age: The USDOJ West Coast Digital Currency Summit

Kyle Burgess

On behalf of Consumers' Research, I had the privilege of attending the first U.S. Department of Justice-sponsored dialogue on digital currencies and blockchain technologies. While I've heard that FinCen (the U.S. Department of Treasury's Financial Crimes Enforcement Network) held a digital currency conference in the past, I believe this event was the first government-led effort to foster inclusive and meaningful discussion between regulators, law enforcement agencies, and industry representatives.

Held at the Federal Reserve Bank of San Francisco, the event boasted roughly 175 participants (small for bitcoin, huge for government budget restrictions) representing federal and state regulators and law enforcement agencies, various prominent digital currency and blockchain companies, a handful of venture capitalists and financial institutions, and even a few consumer representatives – yours truly for Consumers' Research and a colleague from the Consumer Financial Protection Bureau (CFPB).

The summit opened with remarks from Brian Stretch, Acting U.S. Attorney, who described the event as “an opportunity for the various actors in the space to come together and learn from each other.” After thanking organizers for their contributions and participants for their time, he gave the floor to attorney Jason Weinstein of Steptoe and Johnson LLP, who discussed the recent launch of the Blockchain Alliance – “a nonprofit organization founded by the Chamber of Digital Commerce and Coin Center to serve as a public-private forum for the Bitcoin community and federal law enforcement agencies.” Weinstein, director of the Alliance, described it as a tool to help fight criminal activity on the blockchain and identified several of the companies present as members of the alliance.

The first and last of the four panels featured representatives of Xapo, Coinbase, BitFury, Ripple, Circle, Elliptic, R3CEV, Chain, Blockstream, and Citibank. For those seasoned in digital currency and the blockchain, these panels echoed much of the sentiments expressed at similar events over the last

year, with greater emphasis on compliance programs and how these companies can and do collaborate with law enforcement agencies to mitigate crime conducted utilizing their services.

While compliance efforts are vital to curbing the use of digital currencies in illicit activities, Xapo CEO Wences Casares highlighted that users of bitcoin have the option of using wallet services (such as Xapo, Coinbase, Circle, and exchanges), which have controls in place, such as requiring customers to provide personally identifiable information and to link their bank accounts to their wallets, to help them monitor transactions and report suspicious activity to the appropriate officials; however, bad actors are unlikely to use these companies' services, because they would not be able to mask their activities. Instead, most of the bitcoin transactions on the blockchain are conducted without the use of wallet services, and therefore in effect are not regulated.

Casares points out that of the 14 million coins in the bitcoin environment, roughly 4 million are in the regulated bitcoin environment and 10 million are in the non-regulated environment, which is under 30% of the coins in use on the blockchain. He further emphasizes that of the 100,000 daily transactions conducted in bitcoin (amounting to roughly \$100 million), the percentage of value or volume transferred in the regulated environment is even smaller than 30%. Casares cautions that while we are moving in the direction of shifting more of these transactions into the regulated bitcoin environment, we need to be careful that overly strict or burdensome regulatory compliance does not drive more transactions back to the unregulated bitcoin environment.

The mid-day panels featured the heads of FinCen and the California Department of Business Oversight (DBO), a senior representative of the Securities and Exchange Commission (SEC), and representatives from the FBI, DOJ, DHS and Secret Service. Rather than tight lips and prepared remarks, the majority of these panelists were candid and spoke positively about the opportunities offered by bitcoin and blockchain

technologies. They noted challenges and reservations, but were largely supportive of bitcoin and blockchain businesses, particularly those taking an active role in collaborative efforts with law enforcement and compliance.

To the members of the regulatory panel, we posed the following question:

“In the last panel, some of the businesses mentioned that the cost of compliance, for them is manageable because they are funded, but for small businesses is astronomical, and I’m curious, is there any effort from law enforcement [and regulators] to help mitigate that cost for businesses, because I think a lot [of them] would argue that they are being forced to pay the cost of law enforcement by doing this compliance and that cost then gets passed onto consumers and limits consumer choice, so I was just curious what efforts are being made to help with this from your end?”

The first response noted that from a federal standpoint, registering with FinCen is free, because there is no licensing regime, so the cost comes from the need for compliance staff which the government (i.e. tax payers) obviously would not fund. Maybe I should have been clearer in my question – admittedly, it was a bit circuitous – but this is not what I was asking. The second response on the state level was cut and dry – businesses need to get over the cost of compliance if they want to do the kind of business (i.e. offering financial services) that requires licenses designed to protect consumers and mitigate fraud and money laundering – even if those costs are greater than 20% of their staffing/overhead. Again, unfortunately not what I was driving at.

I was hoping to hear that these agencies were open to the idea of providing resources to businesses that wish to be compliant and competitive, but are essentially priced out of the industry because compliance costs, according to one panelist, have reached 35% of their operating costs. I certainly don’t expect the government to pay for every start-up’s

chief compliance officer, but it would be a one-time centralized cost for these agencies to develop resources or partner with organizations who offer (free or low-cost) resources on best practices and procedures that businesses could use to achieve regulatory compliance goals, as opposed to each business reinventing the wheel on their own at great expense.

Consumer choice and regulatory compliance should not be mutually exclusive. There has to be a better way to ensure that AML/KYC and other regulations are satisfied without companies designating a third of their resources (time and finances) to compliance. Hopefully, as collaboration among these actors increases, innovation and improved trust will foster a more effective solution. ◀