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Written by **Michael Tennant** on April 20, 2015

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ObamaCare: Stifling Innovation

"The overwhelming majority of the world's health-care innovation occurs in the U.S.," Dr. Scott Atlas noted in an October *Wall Street Journal* op-ed. "This includes ground-breaking drug treatments, surgical procedures, medical devices, patents, diagnostics and much more…. A recent *R&D Magazine* survey of industry leaders in 63 countries ranked the U.S. No. 1 in the world for health-care innovation."

One big reason for the United States' lead in healthcare innovation is that despite much government intervention, until recently our healthcare system — unlike those of many other countries — retained at least some ties to the free market. The way to profit in the free market, of course, is to meet the needs of consumers; and in the healthcare arena, that means coming up with newer, better, and less expensive treatments for the myriad maladies that afflict the human race.

ObamaCare changes all that. The misnamed Patient Protection and Affordable Care Act (ACA) distorts the healthcare market with its taxes, subsidies, cost controls, and other regulations, causing resources to be directed toward political rather than economic ends.

The effects of the ACA have already been felt in the insurance market, where premiums have increased and choices have been restricted, and in employment, where companies are shedding staff and shrinking employees' hours to avoid the law's mandates.

The law's effects on other sectors have, however, been largely overlooked by most media outlets. One of "the least noticed" of these effects is ObamaCare's "threat to innovation," declared Atlas, a physician and senior fellow at Stanford University's Hoover Institution. Atlas is hardly alone in sounding the alarm over the ACA's impact on medical innovation. Many experts concur that the law is likely to slow innovation in the United States, which will surely have negative, though often difficult-to-detect, consequences for Americans' health.

Device-ive Tax

Perhaps the most blatant anti-innovation provision in the ACA is the tax on medical devices. In an effort to partially pay for the law's massive spending hikes, Democrats included a 2.3-percent excise tax on revenue — not profit — from the sale of medical devices.

That tax, which took effect in 2013, "has taken a heavy toll on the [medical-device] sector, hurting pricing decisions of companies and subjecting them to tremendous margin pressure," according to a December report from Zacks Investment Research. The 2.3 percent skimmed off the top has "wip[ed] out almost a quarter of the profit" of device manufacturers, the website said, noting that there has been "a slew of divestments" in the sector, many of them "specifically to offset the tax."

"It's clearly without any comparison the most difficult situation we've had to face in 34 years," Fred Lampropoulos, CEO of Utah-based device maker Merit Medical Systems, told Salt Lake City's KSL-TV in

2013.

At the time, Lampropoulos estimated the tax would cost his company as much as $7 million a year.

“You take that kind of money out of a company and something has to give,” he said, “and it’s basically research and development or marketing, and those are jobs.”

A survey taken at the end of 2014 by the Advanced Medical Technology Association (AdvaMed), a trade group, found that 18,500 device-industry workers had already lost their jobs as a result of the tax and that the industry plans to forgo hiring nearly 20,500 employees over the next five years. Citing a 2007 report by healthcare consulting firm the Lewin Group claiming there were four indirect jobs in the general economy for every direct job in the device industry, AdvaMed calculated that the device tax could cost as many as 195,000 jobs. And that may understate things: 46 percent of survey respondents “said they would consider further reductions in employment if the tax is not repealed.”

The survey also found that more than half of respondents had reduced their R&D spending as a result of the tax and that three-quarters “said they had taken one or more of the following actions in response to the tax: deferred or cancelled capital investments; deferred or cancelled plans to open new facilities; reduced investment in start-up companies; found it more difficult to raise capital (among start-up companies); reduced or deferred increases in employee compensation.”

“The reduction in R&D is especially troubling as investments in research today are the cures and treatments of tomorrow,” Stephen Ubl, president and CEO of AdvaMed, said in a press release accompanying the survey results. “The effects of this tax could have a damaging ripple effect for decades to come if left unaddressed. This tax is not just a tax on medical technology companies. It’s a tax on medical progress.”

Indeed it is. According to Atlas, between 2012 and 2014, U.S. R&D spending growth averaged just 2.1 percent, slightly more than a third of the average over the previous 15 years, while R&D spending in other countries increased more rapidly. Not all of that can be blamed on ObamaCare, but certainly a significant amount can: The CEO of one of the largest U.S. healthcare companies told Atlas that his company’s 2013 device-tax bill exceeded its entire R&D budget. That’s wealth transfer, not investment in the future.

The tax harms device makers both big and small, said Robert Grajewski, president of Edison Nation Medical, a company that helps medical inventors bring their products to market. Big companies are wary of investing in early-stage innovations “because they know it’s going to cost them significantly to bring these products to the market, and [the device tax] is just another arbitrary tax and toll on that process,” Grajewski explained in an interview with The New American. Instead, he said, they’re waiting for others to prove out their innovations and then buying them up at that stage.

But where are the startups going to get their capital? Since Obama signed the ACA into law, Atlas wrote, “private-equity investment in new U.S. health-care startups has also diminished.” And those that can obtain capital have another problem. “With these startup companies, revenue is king,” said Grajewski. With companies “typically starting at a loss,” he argued, “every dollar is important,” so “just arbitrarily taking two percent, three percent away from a company … certainly is not helpful.”

The device tax, he maintained, “ultimately hurts innovation. It hurts the delivery of care.”

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Penny-pinching Provisions

While the device tax's effects are easy to understand and observe, other ObamaCare provisions may have even more far-reaching but less obvious consequences.

"The Affordable Care Act, from my perspective, has really put front and center the shift in healthcare from a fee-for-service business to one that's more around population housing, keeping a population healthy based on providing a set amount of capital from which then you are in charge of administering that kind of healthcare," stated Grajewski.

That, of course, is the model employed by every "universal" healthcare system in the world, and it inevitably leads to poorer care and rationing in an effort to control costs. ObamaCare, not surprisingly, is loaded with such cost-cutting measures.

For instance, the ACA assigns the secretary of Health and Human Services (HHS) the task of "mak[ing] recommendations" that certain insurers be excluded from offering plans on the exchanges "based on a pattern or practice of excessive or unjustified premium increases," even if those rate hikes are applied only to plans sold outside the exchange. Since the law doesn't define "excessive or unjustified premium increases," insurers are at the mercy of HHS, which has decided that an annual premium increase of 10 percent or more will put an insurer on the "naughty list" and may ultimately mean the company's exclusion from the exchange.

This policy "has significant impacts on what insurers offer … inside the exchanges as well as outside," Burke Balch, J.D., told The New American. Balch, director of the National Right to Life Committee's Robert Powell Center for Medical Ethics, noted that "many of the plans in the exchanges are narrowing their networks dramatically," cutting down on the number of providers, most especially "leading centers of medical innovation." That's because the high-quality research hospitals tend to be among the most expensive.

"These are the research centers, these are the teaching hospitals, these are the places where the toughest and most difficult cases get sent, and these are the places where medical innovation very largely takes place," Balch said. "So over time, if you basically are excluding these top-flight, cutting-edge medical centers from the plans that people are able to get through the exchanges and also creating a disincentive for insurers even to offer such plans outside the exchanges … there's going to be insufficient demand to sustain these cutting-edge medical centers, to sustain these specialists. What happens when that occurs?… They start to go out of business, they start to cut back on the advanced, experimental procedures, and so medical progress slows to a crawl."

Monetary Myopia

The exchanges also suffer from what John Graham, senior fellow at the National Center for Policy Analysis, called "short-term-ism." Because individuals buying coverage on the exchanges can re-enroll in a new policy every year — indeed, HHS actually encouraged them to do so this year because the rates on the benchmark exchange plans had in many instances risen dramatically since 2014 — insurers are focused on how much each covered person is going to cost them over the next 365 days, often to the exclusion of long-term costs, Graham told The New American.

Graham cited the example of two very effective drugs used to treat hepatitis C, Sovaldi and Harvoni.

Those drugs, he said, can cost tens of thousands of dollars for a three-month course of treatment, which seems expensive until one considers that an untreated patient is likely to need other treatments over the rest of his lifetime and quite possibly a liver transplant, which will prove far more costly than Sovaldi or Harvoni.

"So you're talking about spending 60, 70, 80 thousand dollars today to save half a million or more dollars over the entire lifecycle of the treatment," he explained. "Now, in a system where the individual and the insurer only have a one-year-contract, the insurer has no incentive to pay for that because it doesn't capture the benefit of the long-term savings."

ObamaCare's shortsightedness is one of its most significant impediments to innovation. Balch referred to it as "cutting off our nose to spite our face" — forcing healthcare spending below market levels in the short term without realizing the harm it will do in the long term.

"Whenever you have something that is innovative, whenever you have something that is cutting-edge, it tends to start out as extremely expensive," he said. "But what happens is over time, economies of scale kick in, greater efficiency occurs in its production, and the price tends to fall. But unless you have sort of the demand and the opportunity to have that initial high cost, you're not going to get the innovation that then gets to that level."

Other Cure-killers

Another of the ACA's cost-cutting measures — the excess-benefits or "Cadillac" tax, an excise tax on employer-sponsored coverage the government considers too generous — is only likely to magnify the negative effects of exchange coverage. Although the tax is indexed to inflation, healthcare costs have been rising faster than inflation for decades, which means most employer plans are likely to become subject to the tax unless they are scaled back considerably over the coming years. Some employers will simply drop coverage and let their employees buy it on the exchange, possibly chipping in extra (taxable) pay to help cover the premiums. Others will offer only the minimum coverage required by law. Either way, the disincentives to innovation created by narrow networks, low reimbursement rates, and outright refusal to pay for certain treatments can only grow.

The biggest long-term anti-innovation provision of the ACA may well be its expansion of Medicaid. According to the Heritage Foundation, 71 percent of the net increase in individual-market coverage in 2014 was attributable to Medicaid expansion. Medicaid, however, already reimburses healthcare providers at such low rates that only half of family doctors accepted Medicaid patients in 2013, a survey by physician-staffing firm Merritt Hawkins found, and half of those who do see Medicaid patients aren't accepting any new ones. Moreover, while the ACA bumped up reimbursement rates for 2013 and 2014, it did not guarantee those rates into the future, so this year Medicaid reimbursement rates have fallen back to 2012 levels even as healthcare costs have continued to rise. (Some states are paying the difference out of their own coffers this year, but they are unlikely to want to continue eating the extra cost for an extended period.)

Studies have repeatedly shown that patients covered by Medicaid have worse outcomes than those covered by private insurance. Much of this is attributable to Medicaid's meager reimbursement rates. When one's insurance doesn't pay what quality healthcare providers are worth, one isn't as likely to get good or timely treatment. For instance, there have been great strides in treating cancer in recent

decades, much of it due to earlier diagnosis and treatment. But the low reimbursement rates and parsimonious prescription-drug plans offered by Medicaid and by many exchange plans, which Graham said are "more like Medicaid coverage" than private insurance, will tend to lead to later diagnosis and less-effective treatments. Meanwhile, with the revenue stream for specialists such as oncologists drying up as a result of ObamaCare, "there aren't going to be as many of them," Graham said. "America," he asserted in a January *Forbes* piece, "cannot continue to win the war on cancer if Obamacare succeeds in reducing Americans' access to oncologists or cancer drugs."

Another way in which ObamaCare stunts innovation is by mandating "essential health benefits" on exchange plans and requiring them to offer multiple tiers of coverage — the sorts of requirements that only large, established firms will be able to meet. Add to that the fact that subsidies are based on middle-tier (Silver) plans, and, wrote Reuters' Reihan Salam, "low-end entrants that only want to focus on low-cost, limited-network Bronze-level plans won't have that option."

"Obamacare includes many other incumbent-friendly provisions, which lock healthcare providers into existing business models," Salam penned. "That's a shame, as there is nothing about the goal of achieving universal coverage that necessitates making it harder for innovative new business models to take hold." That's true, but as long as that laudable objective is pursued via government compulsion, innovation is bound to suffer.

Then there is the uncertainty associated with a thousand-page law and the tens of thousands of pages of associated regulations that continue to pour forth from Washington. The Obama administration has repeatedly altered deadlines, granted exemptions, and otherwise made an already difficult-to-follow statute virtually incomprehensible. Congressional Republicans have spouted a great deal of rhetoric about repealing and replacing ObamaCare but until recently have followed it up with little substantive legislation. The Supreme Court has modified the law, most significantly in 2012's *NFIB v. Sebelius*, in which the court upheld the ACA's mandates and fines but declared its Medicaid expansion optional for states, and also in 2014's Burwell v. Hobby Lobby, in which the court ruled that closely held for-profit corporations could not be forced to pay for contraceptive coverage for their employees if their owners have religious objections to doing so. The court is now hearing arguments in *King v. Burwell*, which challenges subsidies for health insurance bought on the federal exchange; a decision in favor of the plaintiffs could upset the entire ObamaCare apple cart by making vast swaths of people unable to afford coverage and therefore exempt from the individual mandate.

"That unknown, not knowing what the future may hold, certainly has people worried and hesitant to make moves and make decisions, and that's really slowed down innovation," Grajewski said.

Graham agreed, observing that "we've got an eternity of just arbitrary rulemaking and insider trading basically in Washington, D.C., to decide what our healthcare system looks like," though he also suggested some could be using the uncertainty as an excuse: "Entrepreneurs should not be scared of uncertainty. They should manage the risk and go for it."

But managing risk is exceedingly difficult when the rules are constantly changing. Such a volatile regulatory environment was one of the prime contributors to lengthening and deepening the Great Depression, economist Robert Higgs has argued. In such a climate, businesses and investors simply hold onto their capital until things calm down to the point where they can feel relatively certain that they will get a good return on their investment.

"Not knowing what's coming next," Grajewski averred, "has made people be very hesitant to see where things fall out or where the wind blows, and thus they'd much rather wait and see before adopting new products, new processes, new technology, and even new innovations because they don't want to extend that dollar in a very belt-tightening environment when they don't know if that's what they need to do to survive."

Prognosis for Progress

ObamaCare won't stifle all medical innovation, of course. There will always be those who are driven to succeed despite the obstacles, though much of this success may come from shipping jobs and R&D overseas to avoid the hostile environment here at home. In addition, there are others who will take advantage of the opportunities to innovate in ways that accommodate the newly cost-conscious environment.

"There has been a renewed focus by entrepreneurs and startup companies to really focus on new technologies that help deliver care more efficiently, more effectively, and around this population health-management model," said Grajewski, citing the examples of the "growth in remote patient monitoring equipment" and the introduction of the GuardianOR, a device to prevent operating rooms from accidentally discarding costly surgical equipment, which he claimed is "a multi-billion-dollar-a-year issue."

Few would argue that innovations that cut the cost and improve the quality of care are a bad thing. In fact, it's likely that many such innovations would have occurred even in the absence of ObamaCare, though perhaps it would have taken them a bit longer to come to fruition. But to the extent that such innovations are driven by political considerations rather than consumer needs, capital is diverted to less efficient uses, retarding economic growth. Then, as innovations desired by consumers dwindle, pressure is likely to mount for the government to "invest" in new medical technologies to make up for alleged "market failure," with predictably disastrous results. In the words of *Forbes*' Bill Flax, "Here come the medical Solyndras."

Is all lost, then? Are we doomed to a future of stagnating, rather than advancing, healthcare? Perhaps not. Republicans now control both houses of Congress and have introduced a number of bills modifying or repealing all or part of ObamaCare. Getting them past Democrats in the Senate, who could mount a filibuster given that there are only 54 GOP senators, and then signed by the president is another matter.

One bill that might find its way onto the books is a repeal of the medical-device tax. As of this writing, the House version of the bill has a whopping 276 cosponsors, including 36 Democrats, and the Senate version has 34 cosponsors, including five Democrats. Thus, the bill can easily pass the House, and if just one more Democratic senator supports the bill (assuming all Republicans do), it will be filibuster-proof. It will not necessarily be veto-proof, though amending it to include some offsetting spending cuts might convince Obama to sign it, suggested Graham.

Also, unrelated to ObamaCare but very much related to innovation is the 21st Century Cures Initiative, a bill championed by House Energy and Commerce Committee chairman Fred Upton (R-Mich.). According to Graham, the bill would "reframe the whole national system for researching and developing not only pharmaceutical and biotech but digital medicine, medical devices that could just be apps on

your smartphone, just restructure the whole architecture of the regulatory apparatus to reduce the cost and increase the speed to market of some of these new technologies." That's something that is sorely needed. The Food and Drug Administration (FDA) has become increasingly sluggish and demanding over the years, delaying or denying approval of many promising and even lifesaving treatments — even when they have been approved for use in other developed countries. The agency, Graham says, has "become measurably worse over the last five years," which in part explains why it now costs $2.6 billion to develop a new pharmaceutical, nearly 2.5 times more than it cost just 12 years ago. If shuttering the FDA is not in the cards, then serious reform of the agency is a must if U.S. companies are to continue bringing new treatments to market.

What does the future hold for medical innovation in the United States? "The 2011 PricewaterhouseCoopers Medical Technology Innovation Scorecard found that 'the gap between innovation leaders and emerging economies is rapidly narrowing,'" wrote Atlas. "And that 'although the United States will hold its lead, the country will continue to lose ground during the next decade.'" If America wishes to remain at the forefront of finding new cures for the innumerable ailments that plague mankind, ObamaCare needs to go.

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