



THE PROFIT MOTIVE – A NECESSARY EVIL?

written by Andrew Silverio

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orking in the self-funded healthcare industry, it can be easy for us to develop tunnel vision and focus on cost containment and affordability at all costs, losing sight of other valid interests within and relating to the healthcare market.

Quality of care is an obvious one – if not done properly, reductions in cost can come at the expense of quality (of course, this isn't always the case in healthcare, a product which so often has a great deal of inefficiency built in).

But there are other, less directly related interests which we should keep in mind when we zoom out and look at the broader system, for example in forming policy decisions. The healthcare market is an ecosystem, and like in any ecosystem, one organism becoming too powerful can ultimately be a bad thing for everyone. A super-predator in an isolated system can quickly hunt its own prey out of existence and starve.

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CNBC published an article recently about a disease called nonalcoholic steatohepatitis, or “NASH.” It develops from nonalcoholic fatty liver disease, which has been estimated by the Center for Disease Analysis to impact 89 million Americans, and can lead to cirrhosis, cardiac and lung complications, liver cancer, and death.

As a result of the obesity epidemic, particularly around the western world, the disease is becoming increasingly common, and the National Institute of Health now states that as many as 30 million Americans, or 12 percent of adults, have NASH. It's estimated that by 2020 NASH will surpass hepatitis C as the leading cause of liver transplants in the United States, as increasingly younger Americans, now often in their 20s and 30s, are developing the disease.

As alarming as these numbers are, there is still no FDA approved treatment for NASH. Yet.

With a global market for a cure estimated at \$35 billion (with a b) dollars, pharmaceutical companies are quite literally racing to get new drugs approved and onto the market. There are currently 55 NASH drugs in various stages of clinical trials according to BioMedtracker, so new treatments are clearly on the horizon.

That \$35 billion pot of gold is the sole reason so many companies are sinking so much money into just having a shot at being first to market. The market may be months away from a cure, it may

be a few years away – we're not doctors or medical researchers – but what we can say with confidence is that whatever the timeline is, it would be much longer without that mammoth payoff as motivation.

Manufacturers of new specialty drugs are allowed to charge, and regularly receive payment of, absolutely absurd prices. But in some cases, as appears to be the case with NASH, it is precisely because of this that we will soon have treatment for a disease which would otherwise continue taking lives unchecked.

This ability of manufacturers to charge and receive such high rates for new drugs has also given rise to an entire new sub-industry based around medical tourism and drug importation. In attempting to get patients access to new specialty drugs at a reduced cost to employers, numerous programs aimed at securing generic versions not yet available in the United States are enjoying success under several different models.

These programs run the whole spectrum, from acting to facilitate shipment by a foreign pharmacy in Canada or Mexico to the American patient, or sending that patient to a border to cross over and pick up a drug themselves, all the way to a concierge service where a patient flies first class to the Caribbean, is put up in a hotel, and receives their treatment in a tropical paradise.

The fact that this third option can actually still be significantly less expensive than the patient simply picking up the American version of a drug at the pharmacy down the street from his or her home is quite telling.





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Other types of cost-containment efforts take aim at getting the amounts a plan has to actually pay for these drugs under control. Again, these programs vary greatly and can take the form of exclusions for certain specialty drugs, exclusions for all specialty drugs, or unique cost-sharing structures where copayment amounts change based on whether payment might be available from another source or based on the particular drug.

Seemingly recognizing the impossibility of an individual without insurance paying for these drugs out of pocket, manufacturers implement assistance programs to help cover patient copayments, or offer discounts or rebates for those who pay completely out of pocket. Other programs aim to identify when these programs might be available and steer that monetary benefit back toward the health plan.

The fact that all these different approaches are necessary illustrates an important principle which is often overlooked – the profit incentive to develop new drugs and therapies.

America is a global leader in developing new therapies and is by far the biggest healthcare spender per capita and arguably guilty of the greatest waste. Can the former continue to be true without the latter?

If not, to what extent are we willing to sacrifice innovation and the development of new therapies for those few with no remedies available for their illnesses, in order to ensure that the masses can receive vital routine care in an affordable way?

Food for thought. ■

Andrew Silverio joined the Phia Group, LLC as attorney Third Party Liability Lawyer in the summer of 2014, dealing with a variety of issues such as Medicare recovery and Medicare COB, class action recovery, and other opportunities to recoup funds for benefit plans. In addition to conducting research into novel and developing areas of the industry, he expanded his focus into provider relations, dispute resolution, and cost containment. He now serves as the company's Compliance and Oversight Counsel, handling some of the most complex consulting issues and assisting with compliance and regulatory issues, both internal and external.

Andrew attended Berklee College of Music in Boston, earning his B.A. in professional music. He then attended Suffolk University Law School, graduating with an intellectual property concentration with distinction. There, he took the step into the healthcare realm of the legal world, serving first as an editor and content contributor, and then on the executive board of the Journal of Health and Biomedical Law. Andrew is licensed to practice in the Commonwealth of Massachusetts.

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