

Vaccines in the Trump era

LONDON, UK----1st February 2016----ExpertREACT. The fringe beliefs of a new US president bring concern to vaccine stakeholders. For the industry, pediatric vaccines, given around the age of autism diagnosis, make up a large proportion of yearly revenues. All eyes to Tom Price.

Most people are aware that the new US president, Donald Trump has made erroneous claims that vaccines cause autism and are a threat to our children. But even before Trump's inauguration the anti-vaccine movement had already caused considerable damage to an important public health program that each year saves thousands of lives. The statistics are disturbing. One recent US survey indicated that one in ten Americans believes vaccines are not safe and 30% of respondents said parents should be able to decide not to vaccinate their children (1). Such beliefs and so called "vaccine hesitancy" are now responsible for a resurgence in various childhood diseases e.g. measles that were once under control. In 2015, the US Centers For Disease Control and Prevention reported ten times the amount of measles cases (667) than reported in 2010 (2).

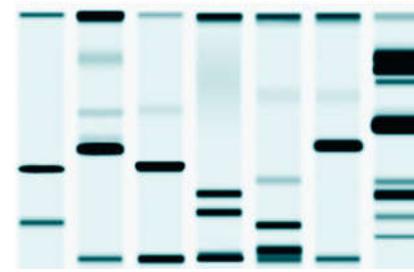
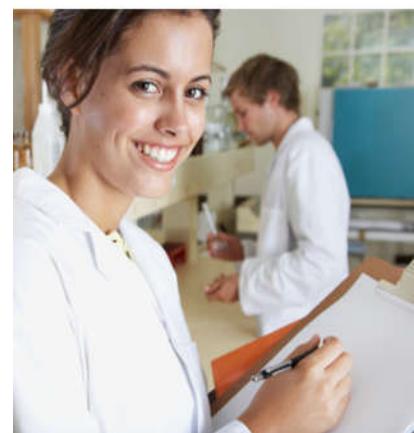
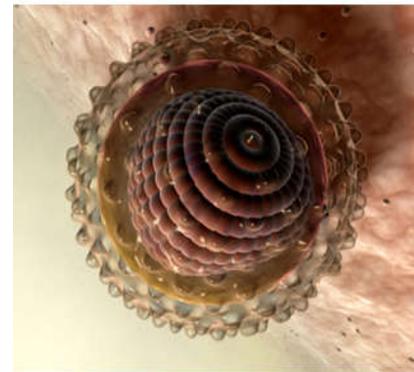
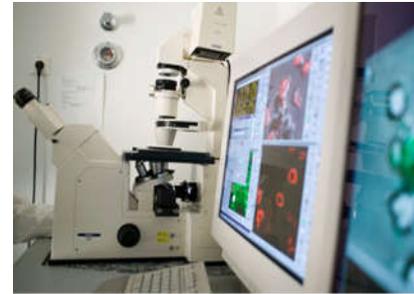
Why does the anti-vaccine movement persist? The vaccine autism story, initiated by the infamous Andrew Wakefield (3) has been disproved on many occasions by reputable bodies who in fact studied thousands more children than the twelve investigated in the retracted Lancet 1998 article. There is still no scientific evidence that vaccines cause autism. Autism usually can be identified by age 2, the same age when many vaccines are given (CDC figures).

The anti-vaccine movement thrives for many complex interconnected reasons. One of them is that a proportion of the public simply do not trust central government decisions. High profile individuals such as celebrities and politicians have recognized this under-current and have publicly given the movement their backing. Whether they believe the science or not, their viewpoints are noted on a massive scale. Misinformation affects public perception of vaccines.

Like any industry heavily centred on scientific or technological advance, vaccine manufacturers have experienced setbacks. The withdrawal of Wyeth's rotavirus vaccine (Rotashield) in 1999 (4), a 1976 swine flu influenza mass vaccine campaign associated with Guillain-Barré syndrome (5), an increased risk of narcolepsy following Pandemrix during the 2009 H1N1 influenza pandemic (6). The examples are many. Governments overspent on influenza pandemic vaccine contracts and were forced to re-negotiate terms after the 2009 pandemic itself was mild. In 2015, the seasonal vaccine was found to have low effectiveness. The US ACIP voted down LAIV during the US 2016-17 season (7). Conspiracy theorists love such examples. They believe powerful companies influence politicians to force upon the public dangerous vaccines they don't need. With infectious diseases, we err on the side of overreaction.

But as much as the public fears vaccines, when faced with danger they also appear happy when governments provide new vaccines. In the UK, public outcry put huge pressure on the government to introduce a newly developed meningitis b vaccine. The decision making Joint Committee on Vaccination and Immunisation (JCVI) had previously deemed the vaccine non-cost effective. In June 2015, it was announced that the vaccine would be given to all UK babies when they reached two months of age. The program is a world first with no safety concerns identified to date (8). Meningitis due to *Neisseria meningitides* is very rare (0.14-0.24 per 100,000 cases US 2006-2007, all ages). It is so rare that the US ACIP committee refused to introduce Men-ACWY conjugate vaccines to the healthy US infant schedule as the potential benefits did not outweigh the risks (9). There is still no infant meningitis b US program. These are not the actions of a 'trigger happy' government willing to pump children with needless vaccines. Safety is paramount.

President Trump has appointed Tom Price to head up the US Department of Health and Human Services (HHS). There is also talk he may choose Robert F. Kennedy to chair a controversial commission on vaccine safety. Focusing on Tom Price, a republican; Price has spent twenty years as a surgeon and should understand evidence based policy. However, it seems more of Price's time could be focused on rolling back Obamacare, one of Trump's key pre-election pledges. Groups have made efforts to pin down Price on his attitudes to vaccines. While non-committal, news articles suggest Price believes vaccines have 'an important role in public health'. But people fear cuts to Section 317 vaccine federal funding worth ~\$600m/yr.



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What should the vaccine industry do considering a new president in their biggest market? There is no doubt that President Trump's fringe beliefs will influence the industry. Already he has met with Pharma executives and stated he wants lower prices for drugs. Some view this is not an unreasonable request in light of clear examples of price gouging e.g. EpiPen (**10**), but aren't vaccines different? As a businessman, Trump should understand that vaccines are a low cost public good that reduce disease and importantly, its cost burden. On top of that, industry drives innovation and innovation should be rewarded.

For many years, the vaccine industry has been conscious of pediatric "schedule crowding" and perceived safety concerns. Marches towards combination products to lessen injections, the removal of preservatives and intranasal delivery (influenza) have all sought to reduce parental fear. Strategies for other childhood diseases such respiratory syncytial virus (RSV) and Group B Streptococcus (GBS) seek to protect the infant by vaccinating the mother. Developers already understand the barriers to introducing new pediatric vaccines. This is not a new dynamic but now it has taken a serious turn.

To some extent, risk has already been limited in the future vaccine industry. Companies now have diversified product and R&D portfolios focused on vaccines for adolescents, adults and the elderly where concerns about autism are less relevant. Indeed, new vaccines to protect children against diseases such as dengue, Zika (R&D), Enterovirus-71, Japanese encephalitis are not intended for the US infant population. Other governments and supra-national organizations make decisions there. For existing US sales of pediatric products, which is a significant chunk of yearly revenues, one can only hope that common sense prevails. Bacteria, viruses, and parasites don't listen to politicians. They kill indiscriminately.

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Sources: Corporate Press Releases and the below

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