

Paul Offit Conflicts of Interest

Paul Offit is Chief of the Division of Infectious Diseases and the Director of the Vaccine Education Centre at the Children's Hospital of Philadelphia (CHOP). He is also a consultant for Merck, the pharmaceutical company that funds his research chair at the CHOP (\$1.5 million). Paul Offit received a \$350,000 grant from Merck to develop a rotavirus vaccine against gastroenteritis in the 80's - 90's. The Philadelphia Children's Hospital is affiliated with the Medical School at the University of Pennsylvania.

Paul Offit was on the US CDC advisory board that approved the use of a rotavirus vaccine (produced by Wyeth Lederle) for the US National Immunisation Program (NIP) in 1998. At this time Paul Offit held a patent for a competitor vaccine that was being produced by Merck and he was due to make millions of dollars from this decision. The first rotavirus vaccine produced by Wyeth Lederle was used in 1998 but it injured many children and had to be withdrawn from the market in 1999. This led to an investigation by the US Government Reform Committee into the policy-decisions that were being made by the CDC and the FDA. The government investigation found that the FDA and the CDC are industry dominated bodies that do not enforce conflict of interest rules.

In 2006 when Merck's rotavirus vaccine - RotaTeq - was approved by the FDA, Paul Offit received patent rights with his co-inventors Fred Clark and Stanley Plotkin. This entitled them to receive on-going royalties from the Children's Hospital of Philadelphia (CHOP) and the Wistar Institute to whom they ceded their inventor rights. These institutes have collaborated in developing this vaccine since the 80's. When the vaccine was approved by the FDA for the US National Immunisation Program (NIP), Offit received millions of dollars in royalties yet he had been allowed to be involved in the decision-making process in 1998 when the vaccine was protected by patent and undergoing clinical trials with Merck. When CHOP sold its royalty interest in RotaTeq in 2007 it was worth \$182 million.

Paul Offit is clearly not a dis-interested expert and yet he is the face of the US government's advocacy for the 'safety and efficacy' of vaccines and for the debunking of the theory that vaccines are a cause of autism. This link has not been debunked because government and

industry have not funded the studies that would prove that vaccines do not cause autism. In 1999 the US Government Reform Committee found that there were no standards of COI within the FDA and the CDC expert advisory committees. Even if a member owned up to \$100,000 in stock or was paid \$250,000 a year by the affected company the conflict would be waived. This situation was known in 1992 when the Institute of Medicine called for changes but the recommendations were not acted upon.

In fact a new law was added to the ethical guidelines in 1997 that allows the FDA to add official industry representatives to advisory committees. As COI are not enforced in these organisations it is clear that policy decisions are not being made with unbiased science. Board members are making 'value judgements' on the welfare of the public which also bring large financial rewards to themselves. This has been described by Krinsky (2003) as self-serving, nepotism, abuse of power, self-dealing or insider-trading and is a breach of the trust the public has in government regulators.

References:

Krinsky S. 2003. *Science in the Private Interest: has the lure of profits corrupted biomedical research?* Lanham MD: Rowman and Littlefield.