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# FEATURE

# The unofficial vaccine educators: are CDC funded non-profits sufficiently independent?

Vaccines are considered one of public health's greatest success stories. But is all promotion of vaccines necessarily a good thing, or does it depend on the details? **Peter Doshi** investigates the semi-transparent world of vaccine advocacy organizations

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Vaccination programs have long been a centerpiece of public health activity. But policies of compulsion have always been controversial. Against a backdrop of recent measles outbreaks, France and Italy moved this year to mandate certain vaccines for school entry.<sup>12</sup> There's even a renewed push for mandates in the UK,<sup>3</sup> where public health leaders have long resisted compulsory vaccination on the grounds that it undermines the trust between the public and healthcare professionals and is ultimately counterproductive.<sup>4</sup>

The debate is also alive in the US. Although all states require vaccination as a condition for entry to school, most also allow exemptions for families with non-medical philosophical or religious objections. Overall, childhood vaccination levels remain at or near historically high levels, with under 1% of toddlers receiving no vaccines.<sup>56</sup> But beneath the broad national trends there is geographic variation in coverage,<sup>6</sup> and survey data have documented that parental concerns over vaccination safety and timing are common, even among those whose children receive all recommended vaccines.<sup>7</sup>

In 2015, a US federal advisory committee warned that public confidence in vaccines cannot be taken for granted,<sup>5</sup> and some prominent vaccine advocacy organizations are pushing for greater compulsion. But are these groups—which present themselves as reliable sources of information—providing the public with independent information?

### Removing the ability to opt out

Two years ago, California state legislators passed a law removing the personal belief exemption that had previously allowed families to defer or decline mandated childhood vaccinations.<sup>8</sup> In doing so, California became the third state to remove non-medical exemptions, following Mississippi and West Virginia.

The debate leading up to the bill's passage had been highly contentious, well publicized, and ultimately passed on a mostly party line vote.<sup>8</sup>

Every Child By Two (ECBT) is one prominent American vaccine advocacy organization that pushed for bill. "We are elated that the California legislature will pass SB277 [California

Senate Bill 277] into law, knowing that it will protect the lives of the school children of your state," it wrote in a letter to the governor.<sup>9</sup>

The American Academy of Pediatrics (AAP) had also backed the bill. "Requiring vaccination is based on the same principle that causes schools to prohibit a child with an active fever from attending class ... it should not be an independent decision by each parent regarding non-vaccination and school attendance," the AAP California chapters wrote in a letter supporting the bill.<sup>10</sup> And in 2016, the 66 000 member national parent organization called on all states to pass laws that remove non-medical exemptions to school entry vaccine requirement.<sup>1112</sup>

Immunization Action Coalition (IAC), another major vaccine advocacy organization, runs one of the web's most visited sites for free vaccine information for healthcare providers. It also uses its website to advocate for increasing rates of influenza vaccination among healthcare workers through mandates, maintaining an "influenza vaccination honor roll" of more than 600 organizations as "stellar examples of influenza vaccination mandates in healthcare settings."<sup>13</sup>

## Who are the vaccine educators?

IAC, ECBT, and AAP have a few things in common. They are all non-profit organizations with large online presences that promote themselves as sources of reliable information on vaccines. They also receive funding from both vaccine manufacturers and the Centers for Disease Control and Prevention (table 1...).

And, in their advocacy for compulsory vaccination, they all have in common a goal that pushes beyond official governmental policy and, in the case of influenza vaccines, the evidence.

# Education or lobbying?

Officially, the CDC is neutral on vaccine mandates,<sup>14</sup> and the agency steers clear of directly influencing state law, telling *The BMJ*: "CDC's policy is to not take positions on state-specific legislation."

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But the CDC gives money to non-profits that actively work in this void. Presumably, these activities are funded from non-CDC sources, as US federal law prohibits the use of CDC award money for lobbying,<sup>15 16</sup> a prohibition that "includes grass roots lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives to urge support of, or opposition to, proposed or pending legislation," according to CDC policy.<sup>17</sup>

Did ECBT and AAP's support of the California bill cross a line for the CDC? CDC's sustained financial support of both organizations suggests it did not. Indeed, at the time of the California bill, the CDC's top vaccine official sat on ECBT's board of directors,<sup>18</sup> and continues to do so.

One of the non-profit's use of evidence is also questionable. Multiple reviews have found insufficient evidence that mandatory influenza vaccination for healthcare workers has benefits for patients.<sup>19-21</sup> As one team of systematic reviewers put it, "evidence from observational studies suggests that a vaccine mandate increases vaccination rates, but evidence on clinical outcomes is lacking."<sup>19</sup>

But IAC stands by its flu vaccination campaign telling *The BMJ*: "While there is debate and research directed at assessing the nature and degree of benefit that vaccinating healthcare workers confers to patients, we are not aware of any definitive and universally accepted study showing a complete lack of benefit."

### Spotty disclosure

How much funding the vaccine advocacy non-profits receive from vaccine manufacturers is hard to pin down, but it seems to be substantial. Federal tax filings show that ECBT gets some funding from vaccine manufacturers, but the amount is not documented. Of its \$1.1m (£840 000; €940 000) in revenue in 2015, over \$800 000 was from non-governmental sources. ECBT's website does not disclose its funding sources, and it refused to answer *The BMJ*'s queries about how much it receives from vaccine manufacturers.

IAC's website, by contrast, lists vaccine manufacturers AstraZeneca, GlaxoSmithKline, Merck Sharp and Dohme, Pfizer, Sanofi Pasteur, and Seqirus among its "supporters and partners." But the website does not list contribution amounts, and IAC was unwilling to disclose the numbers. However, tax filings that the organization did share with *The BMJ* indicate \$1.3m in non-governmental contributions in fiscal year 2016.

The lack of disclosure means it is hard to know what strings, if any, come attached to the funding and how the money was used. Past tax filings indicate that Wyeth and Novartis have provided funding for ECBT's websites VaccinateYourFamily.org and VaccinateYourBaby.org.

And in one case which exemplifies the tangled financial relations between CDC, vaccine manufacturers, and vaccine advocacy organizations, vaccine manufacturers have also funded a coalition that aims to increase the federal government's budget to keep up with the rising cost of the growing vaccination schedule (box 1).

The AAP is a far larger organization than IAC or ECBT, and its remit stretches into many areas of child health. But understanding which external groups fund the AAP's vaccine efforts was initially not much easier than for the others. The organization directed *The BMJ* to an annual publication that lists its donors, which it since added as a link on its funding page.

In its most recent 2016 annual giving report, AAP lists numerous corporate donors, including vaccine manufacturers

GlaxoSmithKline, MedImmune, Merck, Pfizer, Sanofi Pasteur, and Seqirus. Corporations that gave at least \$1m include Mead Johnson Nutrition, Merck, Nestle Nutrition, and Pfizer—relations that have recently drawn criticism.<sup>22</sup>

But the report omits grant funded projects, which helps conceal the substantial funding AAP receives from government, including the CDC.<sup>23</sup>

According to recent tax filings, just over half of the academy's contributions—around \$16 million—were from federal government. The CDC has been a steady funder, awarding the academy around \$20m since 2009, of which over \$7m was for vaccine related efforts, AAP told *The BMJ*.

The CDC's vaccinations website does not provide any clear account of the money it spends on vaccine advocacy. For example, the CDC was directly funding three of six organizations it "partnered"<sup>24</sup> with on a blog relay for national infant immunization week last year but failed to mention the funding on its campaign webpage. However, the agency does publish financial award data in spreadsheets on its website, in compliance with US federal law.<sup>25</sup>

In addition to AAP, CDC is also a major funder of IAC and ECBT. IAC has received over \$2m from the CDC since 2009 to help increase vaccination rates by creating "external sources of scientific, accurate, and credible immunization information that healthcare providers can use to communicate with parents and the public"<sup>26</sup>

Similarly, for nearly a decade, ECBT has received between \$220 000 and \$275 000 per year in CDC funding, around one third of the non-profit's annual contributions. According to tax filings from 2009-11 (form 990), uses of the CDC funds have included "visits to magazine editors to encourage immunization related stories," "monitoring and responding to parent-focused web blogs," "hosting information calls for 'mommy' bloggers" (box 2), and "exhibiting and providing educational material at a number of professional meetings and conferences."

For Michael Carome, who leads the health research group at Public Citizen, a non-profit health watchdog that accepts no government or corporate money, clear disclosure is an absolute essential.

"I think transparency is critically important so that people can understand who might be influencing or what influences might come to bear on a particular message by the group," Carome said.

To Barbara Mintzes, senior lecturer at the University of Sydney and a leading researcher on conflicts of interest, the issues go beyond mere disclosure. "Should the CDC be funding advocacy groups that so strongly support a specific technology, especially when these groups also receive funding from vaccine manufacturers?"

### The BMJ put the question to CDC.

"CDC maintains strong relationships with many key partners around the country. For partners funded through CDC cooperative agreements, our priority is monitoring the progress of those awardees in meeting their targets and working together to achieve goals. CDC does not specifically monitor other sources of funding for most partners," press officer Kristen Nordlund said.

# Independent information on vaccine policy?

In broad terms, the CDC and vaccine advocacy non-profits share a common goal of increasing vaccination rates. But when it

#### Box 1: As the vaccine schedule grows, so does the taxpayer bill

In the US, where much of healthcare is privatized, the government is a major purchaser of vaccines. Under Section 317 of the Public Health Service Act, the CDC has for over 50 years received federal funding to buy vaccines for underinsured and uninsured priority populations, thereby reducing financial barriers to vaccination.

But funding has not kept pace with the increases in the number and cost of vaccines on the CDC's vaccination schedule. In 1996, CDC recommended vaccination against 10 diseases in 1996. A decade later, that rose to 14.

In response to this situation, in 2006 IAC and ECBT formed the 317 Coalition.

According to its website, the 317 Coalition engages in "grass roots advocacy" and is "solely focused on advocating for increased [Section] 317 funding."

But its website says nothing of its own funding.

Mark Mioduski, principal and director of Cornerstone Government Affairs, the Washington, DC based government relations and lobbying firm that represents the 317 Coalition, told *The BMJ* that the coalition has three part-time staff and a \$75 000 annual budget—and is 100% industry funded.

Over the years, with money from GlaxoSmithKline, Merck, Wyeth, Medlmmune, Pfizer, Novartis, and Sanofi Pasteur, Cornerstone Government Affairs has grown the coalition and achieved substantial increases in CDC's Section 317 funding.

And further complicating the web of financial ties between CDC, manufacturers, and advocacy groups is the fact that the CDC has used Section 317 money to fund vaccine advocacy non-profits. In fiscal year 2016, *The BMJ* calculated that CDC granted over \$2.5m to five members of the 317 Coalition.

#### Box 2: Mommy blogging for the CDC

Like many commercial companies, the CDC sees marketing potential in "mommy blogging." In 2015, it recognized the power of "online influencers, including mommy bloggers, [for] get[ting] the word out about the benefits of flu vaccination for families."

And last year, it came close to purchasing the services of a marketing company that specializes in mommy blogging made to order. The company, Megan Media, posted a sign-up sheet for "CDC Vaccination Awareness Paid Blogging Opportunity" on the internet:

"We are looking for Moms with kids under the age of 2 years old (or who can reach that audience) who want to raise awareness around childhood vaccinations," the ad read. "Please fill in the form below if you are interested and feel free to forward this on to any other influencers you may know who would be interested in spreading the word!"

Megan Media trades in what the advertising world is calling "influencer marketing," predicated on the idea that consumers themselves can be powerful marketers, sometimes in excess of traditional advertising. According to a McKinsey report, "marketing-induced consumer-to-consumer word of mouth generates more than twice the sales of paid advertising."<sup>27</sup>

Ultimately however, CDC decided against it. "In the end, we did not use nor did we pay Megan Media, instead choosing to use internal resources to get the information to parents and others."

comes to the details—which vaccines, when, for whom, and how to achieve those goals—is there a need for independent sources of information on vaccination policy?

*The BMJ* asked IAC, ECBT, and AAP to point to an instance when they had questioned a CDC recommendation. None did. ECBT responded that it is the organization's policy to support official recommendations.<sup>28</sup>

The AAP told *The BMJ* that it "conducts an independent analysis" in formulating its vaccine recommendations. When asked what it what meant by "independent," a spokesperson responded: "I was able to confirm that the concept of 'independence' at AAP means our pediatricians perform their own analysis of the data that is independent of outside groups, including industry or government."

But the reality is that since 2000 AAP's vaccine recommendations have been fully "harmonized" with those of the CDC.  $^{29\,30}$ 

IAC and ECBT both told *The BMJ* that they considered that their organizations provided information that is independent of CDC and vaccine manufacturers (table  $2 \downarrow$ ).

Credible third parties can offer true independent assessment through a critical appraisal of official recommendations on the timing and scope of recommended vaccines. The French non-profit organization Prescrire does just this for drugs, vaccines, and therapeutic and diagnostic strategies. It maintains independence by wholly financing its operations through subscriptions, a fact it prominently displays at the top of its website and on the cover of its magazine.

But do advocacy organizations with financial ties to the CDC and vaccine manufacturers have sufficient distance to offer such a service?

Mintzes told *The BMJ* that "these groups are so strongly pro-vaccination that the public is getting a one sided message

that all vaccines are created equal and vaccination is an important public health strategy, regardless of the circumstances. This is as unhelpful as an 'anti-vaxxer' approach that assumes all vaccinations are harmful. Reality is a little different: some vaccines are enormously important to public health; others are marginal at best and likely best avoided."

The IAC lists itself as well as ECBT, AAP, CDC, and other websites as "reliable sources" of vaccination information.<sup>31</sup> But lost in all the advocacy is any self reflection regarding the institutional structures needed to ensure "reliability."

Organizations interested in providing independent information and analysis must give serious thought to just how to achieve that, noted journalist Gary Schwitzer, who heads HealthNewsReviews.org, a watchdog project that has scored a string of recent victories in compelling organizations to revise their conflict of interest policies.<sup>32</sup>

"My head is spinning listening to this description of the tangled relationships—should we call them co-dependencies?—of these entities," Schwitzer said. Independence is about being free "from outside control or support."

"An antonym for independence is reliance," he said. IAC, ECBT, and AAP are "certainly not financially independent. And it would appear they are also not philosophically and intellectually independent, which is just as important—if not more so—in this discussion."

Ensuring such independence seems an essential first step for any organization that wants to seriously respond to public concerns about the safety of childhood vaccines.

Competing interests: See http://www.bmj.com/about-bmj/editorial-staff/ peter-doshi. *The BMJ* is published by the publishing company BMJ, which is a wholly owned subsidiary of the BMA. BMJ receives revenues from subscriptions, open access fees, advertising, and sponsorship

### Key messages

- Industry funded non-profit organizations are an important provider of vaccine related information for the public and health professionals
- CDC also funds advocacy groups that campaign for influenza vaccination mandates for healthcare workers and for the removal of
  non-medical philosophical and religious exemptions for families of schoolchildren
- The complex public-private funding of vaccine advocacy groups lacks sufficient transparency and raises questions about whether such sources can independently assess official vaccination policy

(see www.bmj.com/about-bmj). This includes revenues from vaccine manufacturers.

Provenance and peer review: Commissioned; externally peer reviewed.

- Arie S. Compulsory vaccination and growing measles threat. BMJ 2017;359;j3429. doi: 10.1136/bmj.j3429 pmid:28729469.
- 2 Coombes R. Europe steps up action against vaccine hesitancy as measles outbreaks continue. *BMJ* 2017;359:j4803. doi:10.1136/bmj.j4803 pmid:29038341.
- 3 Moberly T. UK doctors re-examine case for mandatory vaccination. BMJ 2017;359:j3414. doi:10.1136/bmj.j3414 pmid:28720564.
- 4 Salisbury DM. Should childhood vaccination be mandatory? No. BMJ 2012;359:e2435. doi:10.1136/bmj.e2435 pmid:22589520.
- 5 National Vaccine Advisory Committee. Assessing the state of vaccine confidence in the United States: recommendations from the National Vaccine Advisory Committee: approved by the National Vaccine Advisory Committee on June 9, 2015 [corrected]. *Public Health Rep* 2015;359:573-95. doi:10.1177/00335491513000606 pmid:26556929.
- 6 Hill HA, Elam-Evans LD, Yankey D, Singleton JA, Dietz V. Vaccination coverage among children aged 19-35 months—United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;359:1065-71. doi:10.15585/mmwr.mm6539a4 pmid:27711036.
- 7 Kennedy A, Lavail K, Nowak G, Basket M, Landry S. Confidence about vaccines in the United States: understanding parents' perceptions. *Health Aff (Millwood)* 2011;359:1151-9. doi:10.1377/hlthaff.2011.0396 pmid:21653969.
- 8 McCarthy M. California ends vaccine exemptions on grounds of belief--will other states follow?BMJ 2015;359:h3635. doi:10.1136/bmj.h3635 pmid:26139597.
- 9 Every Child By Two. Take action: ask Governor Brown to sign bill to protect school children from vaccine preventable diseases, 9 Jun 2015. https://shotofprevention.com/2015/06/ 29/take-action-ask-governor-to-sign-bill/
- American Academy of Pediatrics. California. SB 277: Elimination of CA personal belief exemption for school-entry vaccines. 2015. http://aap-ca.org/letter/sb-277-pan-allenelimination-of-ca-personal-belief-exemption-for-school-entry-vaccines/
   American Academy of Pediatrics. State advocacy focus: childhood immunizations. 2017.
- 11 American Academy of Pediatrics. State advocacy focus: childhood immunizations. 2017. https://www.aap.org/en-us/advocacy-and-policy/state-advocacy/Documents/Immunizations. pdf
- 12 Committee on Practice and Ambulatory Medicine, Committee on Infectious Diseases, Committee on State Government Affairs, Council on School Health, Section on Administration and Practice Management. Medical versus nonmedical immunization exemptions for child care and school attendance. *Pediatrics* 2016;359. doi:10.1542/peds. 2016-2145 pmid:27573087.
- 13 Immunization Action Coalition. Influenza vaccination honor roll. 2016. http://www.immunize. org/honor-roll/influenza-mandates/
- 14 Centers for Disease Control and Prevention. Influenza vaccination information for health care workers. 2017 https://www.cdc.gov/flu/healthcareworkers.htm
- 15 Levinson DR. Laws prohibit the use of HHS grant funds for lobbying, but limited methods exist to identify noncompliance. Department of Health and Human Services, 2014. https: //oig.hhs.gov/oei/reports/oei-07-12-00620.pdf

- 16 Department of Health and Human Services. Federal restrictions on lobbying for HHS financial assistance recipients. 2015. https://www.hhs.gov/grants/grants/grants-policiesregulations/lobbying-restrictions.html
- 17 Centers for Disease Control and Prevention. List of additional requirements 2017. https: //www.cdc.gov/grants/additionalrequirements/ar-12.html
- 18 Every Child By Two. Board. 2015.http://web.archive.org/web/20150627062118/http:// www.ecbt.org/index.php/about/article/board
- 19 Pitts SI, Maruthur NM, Millar KR, Perl TM, Segal J. A systematic review of mandatory influenza vaccination in healthcare personnel. *Am J Prev Med* 2014;359:330-40. doi:10. 1016/j.amepre.2014.05.035 pmid:25145618.
- 20 Thomas RE, Jefferson T, Lasserson TJ. Influenza vaccination for healthcare workers who care for people aged 60 or older living in long-term care institutions. *Cochrane Database Syst Rev* 2016;6:CD005187.doi:0.1002/14651858.CD005187.pub5 pmid:27251461.
- 21 De Serres G, Skowronski DM, Ward BJ, et al. Influenza vaccination of healthcare workers: critical analysis of the evidence for patient benefit underpinning policies of enforcement. *PLoS One* 2017;359:e0163586. doi:10.1371/journal.pone.0163586 pmid:28129360.
- 22 Sharfstein JM, Silver DL. Relationship between the American Academy of Pediatrics and infant formula companies. JAMA Pediatr 2017;359:613-4. doi:10.1001/jamapediatrics. 2017.1257 pmid:28464121.
- 23 American Academy of Pediatrics. Stepping forward: 2016 annual giving report. 2017. https://www.aap.org/en-us/Documents/philanthropy\_annual\_report.pdf
- 24 Centers for Disease Control and Prevention. Engaging partners in social and digital activities during NIIW. 2016. http://web.archive.org/web/20161127064057/https://www. cdc.gov/vaccines/events/niiw/activities/partners.html
- 25 Centers for Disease Control and Prevention. Award data. 2017. https://www.cdc.gov/ grants/resources/awarddata.html
- 26 Immunization Action Coalition. Immunization Action Coalition awarded \$1.5 million grant from CDC. Press release, 31 Aug 2016. http://www.immunize.org/press/cdc-awards-grantto-iac.asp
- 27 Bughin J, Doogan J, Vetvik OJ. A new way to measure word-of-mouth marketing. McKinsey Quarterly. April 2010. https://www.mckinsey.com/business-functions/marketing-and-sales/ our-insights/a-new-way-to-measure-word-of-mouth-marketing
- 28 Every Child By Two. Support for the recommendations made by the advisory committee on immunization practices. 2012. http://www.ecbt.org/images/articles/ SupportofACIPReccomendations.pdf
- 29 Centers for Disease Control and Prevention. Past immunization schedules 2017. https:/ /www.cdc.gov/vaccines/schedules/past.html
- 30 Walton LR, Orenstein WA, Pickering LK. The history of the United States Advisory Committee on Immunization Practices (ACIP). *Vaccine* 2015;359:405-14. doi:10.1016/j. vaccine.2014.09.043 pmid:25446820.
- 31 Immunization Action Coalition. Reliable sources of immunization information: where parents can go to find answers! 2017. http://www.immunize.org/catg.d/p4012.pdf
- 32 Schwitzer G. STAT becomes 3rd major organization to revise policies after our scrutiny. *HealthNewsReview* 2017 Sep 28. https://www.healthnewsreview.org/2017/09/statbecomes-3rd-major-organization-revise-policies-scrutiny/

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# Tables

### Table 1| Mission, funding sources, and transparency of funding

Organization	Mission (synopsis)	CDC funding	Vaccine manufacturer funding	List of funders on website	Award value on website
Immunization Action Coalition	"To increase immunization rates and prevent disease by creating and distributing educational materials for health professionals and the public"	Yes	Yes	Yes	Partial*
Every Child By Two	"To protect all children from vaccine-preventable diseases by raising parental awareness of the critical need for timely infant immunizations, fostering the establishment of a systematic method to locate and immunize children, and providing convenient access to immunization services"	Yes	Yes	No	No
American Academy of Pediatrics	"To attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults"	Yes	Yes	Partial†	Partial†

\*The value of CDC awards has been given in press releases, but no sponsor information is included on its funding webpage.

†After a query from *The BMJ*, AAP's funding webpage now links to a 2016 annual giving report that lists funders and dollar range. Government funders are not listed. Similar data are available for past years in *AAP News*, a magazine for members.

Table 2| Response to questions from The BMJ asking whether organizations considered they were providing information that is independent of the CDC and vaccine manufacturers

Organization	CDC	Vaccine manufacturers	
Immunization Action Coalition	Yes	Yes	
Every Child By Two	Yes	Yes	
American Academy of Pediatrics	Declined to answer		