Fiscal Effects of HB19-1312: Undisclosed Costs for CDPHE

FISCAL NOTE

Summary of Fiscal Impact: State Expenditure (minimal), Local Government (minimal)

The bill requires the adoption of federal immunization and medical exemption standards for students to attend school; the creation of standardized forms and processes for medical and nonmedical exemptions; and increased tracking of immunizations and exemptions. It increases state and local government workload on an ongoing basis.

Appropriation Summary: No appropriation is required.

2019-2020 Colorado Department of Public Health & Environment (CDPHE) budget will have to include:

A new or revised vendor RFP and contract will be needed for the Colorado Immunization Information System (CIIS) expanded scope of work. = $750,000

- Software programming for new data entry, user interface and reports
- Beta testing with each categorical user of the system (i.e. local health departments, providers, schools and software revisions)
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- Costs for off-site server

$750,000

Staffing at local health departments for the face to face meetings of first time filers for exemptions = $1,216,000

- Data entry of hand collected exemption forms into CIIS
- Beta testing of system by local staff and training costs
- Costs herein are estimated by taking the Larimer County estimate of additional 1150 staff hours = .50 FTE at a minimum of $38K with employer share of salary costs, x 64 local offices, some offices using more time, others less. (.50 x $38,000) x 64 offices = $1,216,000

$1,216,000

Creation, printing (color) and distribution of educational materials for health care providers on the benefits of immunizations. = $300,000

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The CIIS will be rich with data that researchers and pharmaceutical companies will want access to. = $100,000

- How much will the staff increase necessary to monitor third party access while protecting private data?
- Does the legislature want to set parameters and restrictions on who can use this data?

$100,000

$2,366,000

COLORADO
HEALTH CHOICE
ALLIANCE

Print | Close Window

Subject: Fwd: HB 19-11312 Local health department funding
From:
Date: Tue, Apr 23, 2019 4:29 pm
To:

Good afternoon Heather,

Thank you for your email and questions. My understanding from a state-wide conference call (Friday 4/19) is the current draft of the bill requires the Colorado Department of Public Health and Environment (CDPHE) or local public health to sign and report exemptions only once. The initial version required this exemption review per each school year. Thus, we estimate the initial school year may require an estimated 1,150 hours of additional staff time. We are estimating a bulk of that staff time will be needed at the beginning of the school year, and temporary staff may be needed to meet this demand. We were also informed that if HB-1312 does pass, CDPHE will make a budget request to the Joint Budget Committee to cover the additional costs for local public health to sign and report on the exemptions. Local public health will look to CDPHE to provide the necessary staff training, and at this time I would only be speculating on the cost. Regarding ACIP schedule, currently, Colorado requires DTaP, Tdap, Hepatitis B, Hib, Pneumococcal, Polio, MMR, and Varicella for school entry. If the bill passes, the additional routine vaccines that would be added are: Meningococcal, Hepatitis A, Rotavirus, HPV and Influenza. We were also told on Friday's call that there may be an amendment introduced to remove influenza and HPV from the requirement.

Please let me know if you have any questions.

Sincerely,

--

LARIMER COUNTY

Tom Gonzales, MPH, REHS
Public Health Director

Health and Environment
1525 Blue Spruce Drive
Fort Collins, CO 80524
W: (970) 498-6714 | M: (970) 278-6300
tgonzales@larimer.org | www.larimer.org

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Attachment J

Fiscal Effects of HB19-1312: Additional Immunizations

PAGE 12

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22 IMMUNIZATIONS.

For every one vaccine the state adopts into the required list:
(Keeping in mind there are over 250 vaccines in development)

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school age children in Colorado schools

$250 for each child =

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1. Convert all optional vaccines in Colorado to mandated vaccines;
2. Restrict criteria for medical exemptions to ACIP criteria only (which excludes medical exemptions based on personal physician recommendations to delay or omit a particular vaccine); and,
3. Register and track personal, religious and medical exemptions which will be held without time limits or clear restrictions for data usage in the state's immunization registry.
4. Reading the GSK annual report, Coloradans will surely see the industry's return to the legislature or directly to CDPHE (if pg 11 , line 16-20 remain in the bill) to increase the number of doses on their premier vaccines through progressive mandates and expanded schedules for full coverage from birth - 18 years of age against two rare diseases, diarrhea and the flu.

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Can Colorado and federal tax payers continue to afford this escalation of health care costs?

*Seven additional shots required if bill passed as written: hepatitis A(2), rotavirus(2-3, and meningococcal(2) immunizations.

Fiscal Effects of HB19-1312: Meningococcal immunizations

PAGE 12

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Increases premiums, affecting employees, employers, small businesses.

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COLORADO
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COLORADO HEALTH CHOICE ALLIANCE

page 1
Attachment J

Vaccines

We are the leading vaccines company in the world, delivering over 2 million vaccine doses every day to people living in 158 countries. Our portfolio and pipeline help protect individuals throughout their lives. We have recently introduced breakthrough vaccines *Shingrix* for shingles and *Bexsero*, the first vaccine for meningitis B.

Progress against our long-term priorities

Innovation

- *Shingrix* launched successfully in the US and Canada
- 23% of 2018 sales came from recent innovations, driven by *Shingrix* and *Bexsero*
- We have 16 candidate vaccines across all R&D phases
- Capabilities in science and new technologies continues to be differentiator

Performance

- Total 2018 turnover £5.9 billion, up 14% AER, up 16% CER
- Grew ahead of the market, strengthening our position as the leading vaccines company by value
- In addition to *Shingrix*, key contributions from our influenza and hepatitis franchises, and *Bexsero*

Trust

- Over 120 million doses of vaccines delivered to Gavi, the Vaccine Alliance, to help prevent pneumococcal disease, rotavirus and cervical cancer
- 270 million doses of oral polio vaccine delivered to UNICEF for the Global Polio Eradication Initiative
- Positive results from candidate TB vaccine in phase IIb trial

Innovation

Our Vaccines business has 16 innovative candidate vaccines. We balance our focus on this robust pipeline with the active life-cycle management of our existing vaccines, helping to protect more people through expanded indications and geographies.

Our investment in breakthrough vaccines technologies creates a real point of differentiation and will deliver further benefits in the future. We have more than 2,500 vaccines scientists working in three global R&D centres, in Belgium, Italy and the US. This international spread equips us with a diversity of skills and culture, helps to attract the best talent, and opens doors to external partnerships. In 2018, the proportion of our sales from innovations introduced in the past five years was 23%.

#1

23%

We are expanding our capabilities to become a stronger player in the world's largest vaccines markets, the US and China. To achieve this goal, we are simplifying complexity across the business, reducing R&D timelines and developing a more dynamic culture. In September, Roger Connor became the new President, Global Vaccines.

Delivering best-in-class innovation

Shingles

In 2018, our breakthrough shingles vaccine, *Shingrix*, was recognised as the most successful biopharma launch in the past 10 years in North America[1]. In June, Canada's National Advisory Committee on Immunization (NACI) made a strong recommendation for *Shingrix* to be offered to people over 50, following a similar opinion in the US in 2017. In March, *Shingrix* received licensing approval in the EU and Japan, and in May we launched it in Germany. In December, the Standing Committee on Vaccination in Germany, STIKO, recommended *Shingrix* for all people over 60 and for those over 50 with an immune-compromising condition or severe underlying disease. The vaccine was approved in Australia in July 2018. In line with our phased launch strategy, we have the detailed capacity plans in place that are necessary to deliver the meaningful increase in doses needed to meet long-term global demand.

Shingrix marks a step change in the prevention of shingles, a painful and potentially serious condition that affects more than one in three people during their lifetimes. It was designed specifically to address the challenge of age-related decline in immunity and is the first approved shingles vaccine to combine a non-live antigen, to trigger a targeted immune response, with a specifically designed adjuvant to generate a strong and sustained immune response. Clinical trials have proven *Shingrix* efficacy of more than 90% for all age groups studied.

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Vaccines continued

Performance

2018 performance summary

Vaccines turnover grew 14% AER, 16% CER to £5,894 million, primarily driven by growth in sales of *Shingrix*, hepatitis vaccines, which also benefited from a competitor supply shortage, and higher sales of influenza products.

The operating margin of 33.0% was 1.1 percentage points higher at AER than in 2017 and 2.5 percentage points higher on a CER basis. This was primarily driven by enhanced operating leverage from strong sales growth, an improved product mix, including the impact of the launch of *Shingrix*, together with further restructuring and integration benefits. This was partly offset by the comparison with the benefit of a settlement for lost third-party supply volume recorded in 2017, increased supply chain costs and increased SG&A investments to support new launches and business growth.

#3

Shingrix recorded sales of £784 million, primarily in the US and Canada, driven by demand and share gains. US sales benefited from market growth in new patient populations now covered by immunisation recommendations and *Shingrix* has now achieved a 98% market share. In the first half of 2018 alone, *Shingrix* performed twice as strongly as the competitor vaccine had during the whole of 2017.

Meningitis sales were down 1% AER but up 2% CER to £881 million. *Bexsero* sales grew 5% AER, 9% CER, driven by demand and share gains in the US, together with continued growth in private market sales in International, partly offset by the completion of vaccination of catch-up cohorts in certain markets in Europe. *Menveo* sales declined 15% AER, 12% CER, primarily reflecting supply constraints in Europe and International as well as a strong comparator in 2017 and unfavourable year-on-year CDC stockpile movements in the US, partly offset by demand and share gains in the US.

Fluarix/FluLaval sales grew 7% AER, 10% CER to £523 million, driven by strong sales execution in the US and improved sales in Europe, partly offset by increased price competition in the US.

Established Vaccines sales were down 1% AER and flat CER reflecting lower sales of DTPa-containing vaccines (*Infanrix*, *Pediarix* and *Boostrix*) due to increased competitive pressures, particularly in Europe, and unfavourable year-on-year CDC stockpile movements in the US, together with lower *Synflorix* sales, reflecting lower pricing and demand in emerging markets. Hepatitis vaccines sales grew 17% AER, 19% CER to £808 million, benefiting from stronger demand in the US and Europe, as well as a competitor supply shortage in the US.

#4

by adding HepA to required vaccines in states like California,
HepA is rare disease.

Focusing on growth markets

In 2018, we strengthened our position as the world's leading vaccines company by value. Sales grew ahead of the market, increasing our market share and profitability.

#2

Having established our leadership in Europe and emerging markets, we are now focusing on increasing our presence in the world's largest vaccines markets – US and China – to protect more people and improve business performance. The US is our number one priority market and our performance in the US in 2018 has been particularly strong. We welcome the Chinese government's recent steps to fast-track the approval of 'clinically urgently needed' new medicines and vaccines, reflecting its commitment to enabling faster entry of new prevention and treatment options. We look forward to responding to that need with our innovative vaccines in the years ahead.

Creating a simpler, competitive supply chain

We have 13 manufacturing sites, across 10 countries. This international presence enables us to produce our vaccines with flexibility, as demonstrated during the year, when we leveraged our secondary manufacturing network to increase capacity for *Shingrix*.

We have delivered more than 9 million doses globally since launch and we are working hard to build capacity and meet long-term global demand. We continue to target high-teens millions of doses over the next two or three years. To do this, we are undertaking multiple initiatives to boost production across our global manufacturing network in the US and Europe, and at every stage of the manufacturing process from primary antigen production to packaging. These initiatives will ensure sustainable, steady supply growth for the vaccine over the coming years.

During the year, we continued to simplify our supply chain, and discontinued several vaccines that duplicate existing products. Our ongoing investment in our manufacturing network enabled a 10% growth in our filling volume and we maintained our strong focus on the safety and high quality of all our vaccines.

page 3

Meningitis

We are the market leader in vaccines against meningococcal meningitis, with our complementary portfolio of *Menveo*, against serogroups A, C, W, and Y, and *Bexsero*, targeting serogroup B.

#5

In 2018, we continued to consolidate our leadership by broadening the age range that our vaccines cover. In the US, where *Bexsero* is licensed for 10-to-25-year-olds, the vaccine received Breakthrough Therapy Designation from the FDA for children between two- and 10 years old. In June, the European Medicines Agency approved a new, alternative (2+1) dosing schedule for *Bexsero* in infants (in addition to the existing 3+1 schedule), offering healthcare professionals more options to help protect infants from invasive meningococcal disease (IMD) caused by serogroup B and the potential for fewer visits to the doctor for families.

We continued to support external research into meningitis B, including funding the largest-ever study into the adolescent carriage of meningococcal bacteria. The study, led by the University of Adelaide, saw more than 34,000 teenagers being vaccinated with *Bexsero*. The early findings, which are a significant step forward in scientific understanding, show there was a fall in the number of meningitis B cases in South Australian adolescents, but no statistically significant reduction in nasopharyngeal carriage of the bacteria that causes the disease. As such, these preliminary results underscore the need for direct vaccination of vulnerable individuals, particularly infants and adolescents, as the best way to protect against meningococcal B disease.

We advanced our work on new formulations for meningitis vaccines, with our fully liquid *Menveo* candidate vaccine entering phase II clinical trials. The phase III results for the US *Menveo* booster found that it can effectively and safely extend protection four to six years after a primary course of MenACWY vaccine. We also remain committed to the challenging goal of developing a single vaccine to cover the five most common meningitis serogroups of A, B, C, W and Y.

#6

Other priority assets

We are pursuing a full portfolio of vaccines against respiratory syncytial virus (RSV), tailored to the different age groups most at risk of infection from the virus. There is currently no prophylactic vaccine approved for the prevention of respiratory disease caused by RSV, in spite of the significant medical need. Our maternal vaccine is designed to increase antibodies in the mother that will transfer to the baby and help protect them in the first months of life, when the disease is most severe. Our candidate paediatric vaccine, given directly to babies, is designed to induce protection from the disease throughout childhood and, potentially, for recipients' entire lives. In late 2018, we began a phase I/II trial for children, and commenced a phase I study on the maternal vaccine. The US FDA has given fast track designation to our RSV candidate vaccines for pregnant women and older adults, which have just entered clinical development.

By 2030, COPD is predicted to become the world's third-leading cause of death. Our COPD candidate vaccine marks a move away from the traditional concept of a vaccine given to healthy people to prevent a specific disease towards the development of a disease-modifying vaccine that could reduce the frequency of COPD exacerbations and slow down the disease's progress. It combines two antigens from bacteria commonly found in acute COPD exacerbations with our proprietary adjuvant system, ASO1.

The phase I and II studies demonstrated that our candidate vaccine was safe and capable of inducing an immune response. We began a phase IIb (proof of concept) study in Europe and North America in 2017, with efficacy results expected in mid-2020.

In influenza, we are working on a universal (supra-seasonal) vaccine with researchers at Mount Sinai in the US. We also expanded the indications for our existing flu vaccines, with European approval for a paediatric indication for *Fluarix Tetra*.

New technologies

Our success in innovation reflects our unique combination of advanced technologies, scientific experts across three global R&D centres, and external collaborations. Our broad range of technologies includes adjuvant systems, self-amplifying messenger RNA (SAM), bioconjugates, generalised modules for membrane antigens (GMMA) and the chimpanzee adenovirus (ChAd) platform. Such capabilities have the potential to significantly reduce the cost and time of vaccine development and help make radical advances that address unmet medical needs.

External partnerships

Partnerships remain central to our innovation. We have around 150 external scientific collaborations, with most of our 16 candidate vaccines being developed in partnership. Our partnerships and technologies also support our work on tuberculosis and shigella for instance, which is part of our ongoing commitment to developing vaccines against the diseases of the developing world. Such collaborations enable our Vaccines scientists to learn from other leading experts and stay close to emerging technologies and new science.

#7

Vaccines pipeline

Phase	Indication/vaccine
Phase III	*Shingrix* (for immunocompromised)
	✓ *Bexsero* (infants in the US)
	✓ *Rotarix* (PCV-free)
	MMR (in US)
Phase II	COPD
	Hepatitis C
	Malaria (next gen)
	✓ MenABCWY
	✓ *Menveo* (liquid)
	Shigella
	Tuberculosis
	RSV paediatric will this be added by CDPHE?
	HIV
Phase I/II	RSV older adults
	Flu universal
	RSV maternal

page 4

Performance

2018 performance summary

Pharmaceuticals turnover in 2018 was £17,269 million, flat at AER, but up 2% CER, driven primarily by the growth in HIV sales. In the US, sales declined 2% AER but grew 1% at CER, with growth in the HIV portfolio and *Benlysta* offsetting declines in established pharmaceuticals and respiratory following patent expiries. In Europe, sales grew 2% AER, 1% CER, with growth in the respiratory portfolio offsetting the continued impact of generic competition to *Epzicom* and *Avodart*. International was flat at AER but grew 5% CER, with growth driven by HIV and the new respiratory portfolio.

Respiratory sales declined 1% AER, but grew 1% CER, to £6,928 million, with growth from the *Ellipta* portfolio and *Nucala* partly offset by lower sales of *Seretide/Advair* as the market prepares for the entry of a generic. Sales of new respiratory products, comprising *Ellipta* products and *Nucala*, grew 35% AER, 38% CER to £2,612 million.

HIV sales increased 9% AER, 11% CER to £4,722 million, reflecting share growth in the dolutegravir portfolio: *Triumeq*, *Tivicay* and *Juluca*. This was partly offset by the decline in the established portfolio, particularly the impact of generic competition to *Epzicom/Kivexa* in Europe.

Immuno-inflammation sales were up 25% AER, 28% CER in 2018, primarily driven by *Benlysta*.

Pharmaceutical Sales ↓ but Vaccines ↑ 14%

Our Established Pharmaceuticals portfolio includes mainly off-patent medicines. Sales were £5,147 million, down 7% AER, 4% CER, reflecting efforts to maximise the value from this portfolio but also the benefit of certain post-divestment contract manufacturing sales and the first instalment of a 12-month *Relenza* supply contract in Europe.

The Pharmaceuticals operating margin of 33.3% was 1.0 percentage points lower at AER than in 2017 and 0.9 percentage points lower on a CER basis. This primarily reflected increased investment in new product support, the continued impact of lower prices, particularly in respiratory, the broader transition of the respiratory portfolio, and a reduction in royalty income. This was partly offset by the benefits of prioritisation within R&D and a favourable comparison with the impact of the Priority Review Voucher purchased in 2017.

Focusing our resources to accelerate growth

In 2018, we made significant changes to the way our Pharmaceuticals organisation works to accelerate growth and deliver the best results for all our stakeholders.

We refocused our resources, prioritising the major markets such as the US and China, while reducing investment in lower priority markets. We have also prioritised resource behind brands and therapies with the greatest growth potential and which generate the highest revenue. To support our ambitions for the oncology therapies in our pipeline, we strengthened our oncology commercial infrastructure; recruiting more experts in oncology and haematology and co-locating our R&D and commercial teams.

We simplified our commercial, medical and regulatory teams, with fewer complex structures, systems and processes, and clearer accountabilities. This enables greater speed and efficiency and frees local operating companies to focus on customer-facing activities and insights. The savings released by these changes will be reinvested into our priority products and markets.

In recent years, we have significantly strengthened our online resources and in-house medical capabilities to provide bespoke product information for healthcare professionals (HCPs). In 2018, we updated our policy on working with HCPs, following consistent feedback that they value the opportunity to learn about new products through peer-to-peer programmes with expert practitioners who have direct experience of our medicines.

The new policy will ensure prescribers have access to all available information on our innovative products, so they can make fully informed decisions that support better outcomes for patients. When we have new medicines or significant new data we will allow payment to global experts to speak about the scientific evidence, the diseases they treat and their own clinical experience. The change was implemented in the US and Japan in late 2018, and depending on effective implementation and assessment of risk will be implemented in other major developed markets in Europe, North America and Asia from 2019 onwards. To avoid any perceived conflict of interest, we have strengthened our commitment to transparency with new controls and expanded disclosure of payments to individual HCPs.

Creating a simpler, competitive supply chain

Reliable supply is fundamental to enabling growth in key therapy areas. Our Pharmaceuticals supply performance levels continued to improve in 2018 with an on-time, in-full supply to customers rating of 95.3%. All new products were launched on time.

We are adopting a simplified structure and operating model geared to driving performance with increased focus on priority brands and markets, clearer accountabilities and more pace. This has included separating our Pharmaceuticals manufacturing and supply organisation from our Consumer Healthcare network.

We continued to adapt our manufacturing network to support growth, improve competitiveness and meet business and patient needs. We opened a £54 million facility in Montrose, Scotland to supply active pharmaceutical ingredients for our *Ellipta* respiratory medicines, and a £26 million facility in Parma, Italy that will produce fostemsavir, our investigational HIV treatment.

We revised our supply and demand, warehousing and distribution operations to align with commercial priorities and announced manufacturing site closures in Mexico and Bangladesh. Following an extensive review of our cephalosporins antibiotics assets we decided to restructure its supply chain and manufacturing site at Ulverston in the UK. This will help us improve competitiveness and support growth in emerging markets. We continued to simplify our supplier base and product portfolio and are ahead of schedule to reduce our contract manufacturers by 35% by 2021.

The Pharmaceuticals manufacturing and supply organisation again delivered good performance for safety, quality and compliance. There were 55 regulatory inspections in 2018, all resulting in satisfactory outcomes.

see vaccine pipeline under #7

Vaccines i.e. Meningococcal - 3 vaccines
Rotavirus

page 5

Fiscal Effects of HB19-1312: Meningococcal immunizations

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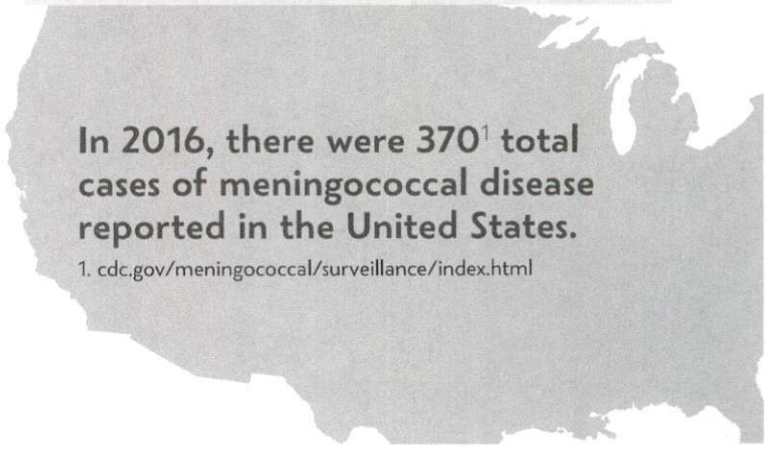

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Take Authority Away from CDPHE to add vaccines

Fiscal Effects of HB19-1312: Additional Immunizations

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1. Convert all optional vaccines in Colorado to mandated vaccines;
2. Restrict criteria for medical exemptions to ACIP criteria only (which excludes medical exemptions based on personal physician recommendations to delay or omit a particular vaccine); and,
3. Register and track personal, religious and medical exemptions which will be held without time limits or clear restrictions for data usage in the state's immunization registry.
4. Reading the GSK annual report, Coloradans will surely see the industry's return to the legislature or directly to CDPHE (if pg 11 , line 16-20 remain in the bill) to increase the number of doses on their premier vaccines through progressive mandates and expanded schedules for full coverage from birth - 18 years of age against two rare diseases, diarrhea and the flu.

Can Colorado and federal tax payers continue to afford this escalation of health care costs?

*Seven additional shots required if bill passed as written: hepatitis A(2), rotavirus(2-3, and meningococcal(2) immunizations.

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