4a - EHEA - SB 808 - BON - LOS.pdf
Uploaded by: Bennardi, Maryland Department of Health /Office of Governmen
Position: FAV

Board of Nursing

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Acting Secretary

March 2, 2021

The Honorable Paul G. Pinsky
Chair, Education, Health, and Environmental Affairs Committee
2 West Miller Office Building
Annapolis, MD 21401-1991

RE: SB 808 – Health Occupations – Licensed Dentists – Administration of Vaccines – Letter of Support

Dear Chair Pinsky and Committee Members:

The Maryland Board of Nursing ("the Board") respectfully submits this letter of support for Senate Bill (SB) 808 – Health Occupations – Licensed Dentists – Administration of Vaccines. This bill authorizes a licensed dentist to administer vaccines to certain individuals under certain circumstances. This bill requires a licensed dentist who administers a vaccine to make certain attempts to communicate certain information to the patient's authorized prescriber and/or primary care provider. SB 808 requires a licensed dentist to complete a board-approved course, file a certificate of completion, and receive acknowledgement of completion before administering vaccines. Additionally, this bill establishes certain continuing education requirements for licensed dentists who administer vaccines.

The Board believes that by allowing licensed dentists to administer vaccines, access to care for Marylanders will increase in a reasonable manner. Individuals who may visit a physician for their vaccine may experience prolonged waiting periods in a crowded lobby. As a result, this may deter individuals from keeping up to date with their vaccine schedules. Licensed dentists will be trained, under the authority of this bill, to administer vaccinations in a safe and clean environment. SB 808 requires licensed dentists to follow a rigorous process of applying and maintaining certification to administer vaccinations. The Board believes that this process will help to maintain public safety by only allowing trained licensed dentists to administer vaccines. Additionally, licensed dentists are required to complete a board-approved continuing education class every other renewal cycle to maintain an active certification. Allowing licensed dentists the ability to administer vaccines to adults and children (within a certain age range) will be essential in fortifying herd immunity against preventable infectious and chronic diseases.

For the reasons discussed above, the Board of Nursing respectfully submits this letter of support for SB 808.

I hope this information is useful. For more information, please contact Iman Farid, Health Policy Analyst, at (410) 585 – 1536 (iman.farid@maryland.gov) or Rhonda Scott, Deputy Director, at (410) 585 – 1953 (rhonda.scott2@maryland.gov).

4140 Patterson Avenue
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Toll free: (888) – 202 – 9861; Local: (410) – 585 - 1900

Sincerely,

Gary N. Hicks
Board President

The opinion of the Board expressed in this document does not necessarily reflect that of the Department of Health or the Administration.

4b - EHEA - SB 808-Dental Board - LOS.pdf
Uploaded by: Bennardi, Maryland Department of Health /Office of Governmen
Position: FAV

Maryland State Board of Dental Examiners
Spring Grove Hospital Center • Benjamin Rush Building
55 Wade Avenue/Tulip Drive • Catonsville, Maryland 21228

2021 SESSION
POSITION PAPER

BILL NO: SB 808
COMMITTEE: Education, Health, and Environmental Affairs
POSITION: Support

TITLE: Health Occupations-Licensed Dentists-Administration of Vaccines

BILL ANALYSIS: The Maryland State Board of Dental Examiners supports Senate Bill (SB) 808 – Health Occupations-Licensed Dentists-Administration of Vaccines. The bill permits a dentist to administer an influenza vaccine to a patient of record who is at least 9 years old, in accordance with regulations adopted by the Board, in consultation with the Department of Health. The bill permits a dentist, with a prescription from an authorized provider, to administer a vaccination that is listed in the Centers for Disease and Control and Prevention's (CDC) Recommended Immunization Schedule to a patient of records who is at least 11 years old but under the age of 18. In addition, a licensed dentist may administer to an adult patient of record, a vaccination that is listed in the CDC's Recommended Immunization Schedule or recommended in the CDC's Health Information for International Travel. The dentist must report all vaccinations to the State's ImmuNet program established under § 18-109 of the Health General Article. Before dismissal of the patient, the dentist must provide the patient with an immunization card and a separate document providing detailed information identifying the vaccine, the dosage amount, possible side effects, instructions for countering possible side effects, and any allergies that the patient may have.

Before administering vaccines, dentists must first successfully complete a Board-approved certification course that includes instruction in the guidelines and recommendations of the CDC regarding vaccinations and receive acknowledgment of course completion from the Dental Board. Dentists must also maintain cardiopulmonary Resuscitation Certification (CPR) and if the vaccination has been ordered by another provider, make efforts to inform the provider of the vaccination. In order to remain eligible to administer vaccines, a dentist must successfully complete a Board-approved continuing education class of at least 2-hours every other license renewal cycle that addresses proper prescribing and disposal of prescription drugs, and adverse interactions and actions of vaccines.

The program to vaccinate is entirely voluntary. Dentists are not required to seek certification to administer vaccines, and if they do not participate in the program, they would not be permitted to

administer vaccines. In addition, in the event that a catastrophic health emergency is declared, the bill permits dentists with or without certification to administer vaccines that have been recognized by the CDC to be effective in combating the particular illness during the emergency. The bill requires the Board to promulgate regulations to implement the law. Finally, the bill amends the definition of "practice dentistry" to include the administration of the vaccines.

POSITION AND RATIONALE:

The Dental Board strongly supports the bill. First and foremost, by allowing dentists to administer vaccines, access to care is increased in the State in a reasonable manner. Dentists will be professionally trained, and vaccines administered in a clean and safe environment. Within the previous 20 years, as the practice of dentistry has expanded, dentists have administered more intraoral and extraoral intramuscular injections than any other health care provider. Many Marylanders see their dentists once or twice a year whereas it may be a number of years before a Marylander sees their physician, especially those who are younger. If a patient has a primary care provider, it is sometimes difficult to obtain an appointment without a prolonged wait. In addition, in the event of a declared health emergency, any licensed dentist would be permitted to administer vaccinations during the pending emergency that have been recognized by the CDC as effective in combating the illness. Parenthetically, dentists in Oregon, Illinois, Minnesota, and Arkansas are already administering vaccines and their programs are considered a success. The curriculum is taught at the University of Maryland Dental School.

At all times, a Maryland dentist's operatory must comply with CDC and infection control guidelines including the wearing of proper PPE. Receiving a vaccine in a dentist's operatory provides a far greater infection control environment than receiving one in a retail outlet. All dentists, even those who choose not to participate in the program, must complete a 2-hour Board-approved course in infection control as a condition of license renewal. Allowing dentists to administer vaccines will be a great benefit to the citizens of Maryland.

There are over 5,000 dentists in Maryland and their potential to administer vaccines has not yet been tapped. Geographically, dentists are widely distributed throughout the State, and are well suited to provide additional care, especially during the current pandemic and beyond. As time progresses, more COVID-19 vaccines that require basic refrigeration will receive FDA-approval and be available to individual health care providers such as dentists to administer.

For these reasons, the Board requests that SB 808 receive a favorable report.

I hope that this information is useful. If you would like to discuss this further, please contact Dr. James Goldsmith, Board President at 301-367-2352, jgoldsm217@comcast.net, or Dr. Arpana Verma, the Board's Legislative Committee Chair at 240-498-8159, asverma93@gmail.com. In addition, the Board's Executive Director, Mr. Frank McLaughlin, may be reached at 443-878-5253, frank.maclaughlin@maryland.gov.

The opinion of the Maryland State Board of Dental Examiners expressed in this support position paper does not necessarily reflect that of the Department of Health or the Administration.

MSDA Supports SB 808 - Lic. Dentists -Vaccines.pdf
Uploaded by: Doherty, Daniel
Position: FAV

The Maryland State Dental Association Supports SB 808 – Health Occupations – Licensed Dentists – Administration of Vaccines

Respectfully submitted by Daniel T. Doherty, Jr. on behalf of the Maryland State Dental Association

The administration of vaccinations is within the scope of practice of Maryland dentists. The administration of vaccines is part of the curriculum of the University of Maryland School of Dentistry and other accredited dental schools in the United States. However, it is appropriate for the State Board of Dental Examiners to regulate the administration of vaccines by dentists. The bill authorizes the Board to develop regulations to govern the administration of vaccine by licensed dentists in a manner consistent with the provisions of SB 808.

Why the administration of vaccines by dentists is safe: Dentists are required to maintain certification in infection control training, personal protective equipment, CPR and they are well trained to handle medical emergencies. Dentists obtain and maintain medical histories of their patients, in which medical conditions, medications and other pertinent information is included. Dentists also have special training to help patients who are phobic about injections and dentists are highly skilled in administering injections.

Why the administration of vaccines by dentists promotes good health among Marylanders: Dental patients tend see their dentist twice a year, which is often more frequently than they see their physician. During these visits the dentist reviews the patient medical history, screens for chronic diseases, inquires about vaccinations and, if requested by the patient, can administer required vaccines. Many Maryland dentists have enrolled in the Maryland Reserve Medical Corp, and have obtained training in the administration of the COVID-19 vaccine. They are prepared to assist in vaccinating our fellow Marylanders as soon as the vaccines are available through local health departments. The inclusion of dentists in vaccination programs will increase the advocacy for vaccinations, and will facilitate the administration of vaccines to Marylanders that do not typically receive vaccines.

The provisions of SB 808: SB 808 clearly outlines requirements concerning a dentist's administration of vaccines to children and adults. It specifically provides when a prescription from an authorized provider is required, and directs the dentist to report all vaccines administered to the ImmuNet Program. It sets out procedures for notifying the patient's primary care provider that the vaccine has been administered.

SB 808 directs that a dentist obtain 1) a signed medical history which includes past vaccinations, drug interactions, known allergies and known complications and 2) a signed consent form that outlines the benefits and risks of the vaccine. It further provides that in non-life-threatening situations, the dentist is to enter immediately the vaccine, dosage amount and

date in the patient's chart. The patient is to be provided an immunization card and a separate document providing important information concerning the dentist, the vaccine, normal reactions, instructions, list of possible side effects etc. Finally, SB 808 establishes educational and other prerequisites a dentist must satisfy before being authorized to administer vaccinations. In addition, the dentist is required to maintain his or her CPR certification.

Conclusion: SB 808 provides prescriptive measures that a dentist must satisfy to be authorized to administer vaccinations. It establishes specific requirements relating to vaccinations based on the age of the patient. It directs notification of each vaccination to ImmuNet and to the patient's primary provider. These and other provisions of SB 808 will enhance the distribution of necessary vaccinations to Marylanders. SB 808 provides the opportunity for patients to be vaccinated by a provider they visit frequently, who is skilled in the administration of injections, and is qualified to reduce stress for needle phobic patients.

The Maryland State Dental Association respectfully requests that SB 808 receive a Favorable Report.

Submitted by:
Daniel T. Doherty, Jr.
March 2, 2021

Support SB 808.pdf
Uploaded by: Doring, Charles
Position: FAV

north bethesda dental associates
founded 1973

CHARLES A. DORING, D.D.S., F.A.G.D.
CLEMENTINA PEREZ-WEST, D.D.S.
ROBERT B. TILKIN, D.D.S., M.S., F.A.G.D.

Testimony in Support of SB 808 – Health Occupations – Licensed Dentists – Administration of Vaccines

Tuesday March 2, 2021

Maryland Senate Health Education & Environmental Affairs Committee

Thank you for the opportunity to provide written today in support of SB 808. My name is Charles Doring and I a general dentist in Rockville Maryland. Along with providing dental care in an office setting, I also provide portable dentistry and I am on the medical staff of several nursing homes in Montgomery County. I am also the Legislative Affairs Committee Chair for the Maryland State Dental Association, the Maryland component of the American Dental Association. I was also recently named to the Provider Advisory Committee of the Maryland Health Smiles (Medicaid) program. I am also a member of the Deans Faculty at our dental school, the University of Maryland School of Dentistry (UMSOD) in the Department of General Dentistry with a dental student externship in Geriatric Dentistry.

I, along with the Maryland State Dental Association strongly urge your enthusiastic support for SB 808 for all the reasons listed below:

1) Administration of Vaccines is being taught at multiple dental school across the country including the University of Maryland School of Dentistry.

2) Definition of scope of dental practice in Maryland statute includes procedures taught at accredited US or Canadian dental schools. SB 808 allows the Maryland State Board of Dental Examines to set the continuing education and certification requirements for existing licensed dentists to administer vaccines in Maryland.

3) Many Maryland licensed dentists have enrolled in the Maryland Reserve Medical Corp, have obtained training in administration of the COVID-19 Vaccine and await deployment as soon as the vaccine is readily available to local health departments.

4) Maryland dentists are required to maintain certification in infection control training, personal protective equipment, CPR, and are well trained in handling emergencies.

5) SB 808 has stringent vaccine training and reporting requirements for those Maryland licensed dentists who choose to administer vaccinations.

6) SB 808 contains the same post vaccination requirements including documentation to the ImmuNet Program as pharmacists.

7) The inclusion of dentist in vaccination programs will increase the ability to advocate for vaccinations and administer vaccinations to population of Marylanders that may not typically receive vaccinations including minorities and individuals in remote locations.

11400 ROCKVILLE PIKE, SUITE 509 · ROCKVILLE, MD 20852
(301) 881-7646 · (301) 881-7688 FAX
WWW.NBDA.DENTIST

8) Marylanders tend to visit their oral health professional twice a year which may be more than other health care providers. During these visits, dentist review patient's health history, screen for chronic diseases, inquire about vaccinations, and administer vaccinations if requested and required.

9) Dentist have special training to help phobic patients particularly as it relates to needles. Dentists provide more injections than most other health occupations.

For these reasons noted above, I ask for a favorable report on SB 808.

Sincerely,

Charles A. Doring DDS

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WWW.NBDA.DENTIST

Testimony-SB 808 Vaccine Administration 3-2-2021

Uploaded by: Grant, Leslie

Position: FAV

Leslie E. Grant, DDS, MSPA
Glen Arm, MD 21057
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TESTIMONY-SENATE BILL 808 POSITION: SUPPORT
Licensed Dentists-Administration of Vaccines
Education, Health and Environmental Affairs
March 2, 2021

Good afternoon. Thank you, Chair Pinsky and Committee members for the opportunity to speak with you today. My name is Leslie Grant. I am a general dentist and presently serve as a member of the Maryland State Board of Dental Examiners. I have been a Dental Volunteer Responder with the Maryland Medical Reserve Corps for more than a decade, and completed their vaccine training earlier this year. I appreciate Senator West's sponsorship of SB 808 and would like to express my wholehearted support. This Bill amends the Dental Practice Act to include vaccine administration and provides requirements for training, informed consent, documentation and reporting. SB 808 will expand the opportunity to contribute to disease prevention in our state, including our most vulnerable populations.

Dental practitioners offer a great safety net for providing vaccinations. We are amongst the most trusted of health care providers. Prevention is a hallmark of our profession. We are adept at educating patients, and are well positioned to address vaccine hesitancy. Dentists are experts in injection administration and precision, we provide more injections than other health care providers and we know how to ameliorate concerns regarding fear of needles. Dentists incorporate proper dosing and dispensing protocols as well as sharps safety in everyday practice.

General dentists typically see patients more frequently than physicians, treat the entire family, and often multiple generations within one family. Dentists offer care in environments where safety is paramount and treatment is delivered by providers who have long term familiarity with implementation of infection control protocols, aerosol safety and proper sequence for donning and removal of personal protective equipment. We provide care across a wide range of settings including private offices, training institutions, correctional facilities, nursing homes and community health centers.

This Bill is good for public health, strengthens collaboration within the health team and provides for an enhanced level of care by an important partner in the health home. In my opinion, the provisions outlined are long overdue. The Surgeon General's report "Oral Health in America" in part asks that we work to change perceptions of oral health, increase collaborations, and increase oral health workforce capacity and flexibility. That report from the year 2000 is twenty years old. Several states have already expanded their scope of practice to include vaccine administration by dentists. The University of Maryland School of Dentistry has already incorporated vaccine training into the curriculum. Vaccine administration by Maryland licensed dentists will be tremendously beneficial for our patients and your constituents.

I request a favorable report on Senate Bill 808. Thank you.

Senator West-SB808-FAV.pdf
Uploaded by: West, Christopher
Position: FAV

CHRIS WEST
Legislative District 42
Baltimore County

Judicial Proceedings Committee

Vice Chair, Baltimore County
Senate Delegation

THE SENATE OF MARYLAND
ANNAPOLIS, MARYLAND 21401

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March 2, 2021

Senate Education, Health and Environmental Affairs Committee
The Honorable Paul G. Pinsky
2 West Miller Senate Building
Annapolis, Maryland 21401-1991

RE: SB 808 – Health Occupations – Licensed Dentists – Administration of Vaccines

Dear Chairman Pinsky and Members of the Committee:

I am pleased to introduce Senate Bill 808. This legislation seeks to authorize a licensed dentist to administer certain vaccines to certain patients under certain circumstances. There are currently 5,000 dentists in Maryland. Many dentists see their patients more often than they are seen by their personal physicians. Patients generally visit their dentists once or twice a year. Dentists also already provide more injections than any other healthcare provider. This legislation would establish a well-regulated system in which dentists could be properly trained and equipped with the tools to effectively vaccinate patients.

Under this bill, no dentist would be required to offer vaccinations to patients. A dentist's decision to offer vaccinations at all and to offer particular vaccinations would be a voluntary one. Dentists that choose to offer vaccinations will be required to take a Dental Board-approved course that includes instruction in the guidelines and recommendations of the CDC regarding vaccines. Then, during every other licensing renewal cycle, the dentist will be required to complete a Board-approved continuing education class of at least 2 hours that deals with vaccination issues.

Senate Bill 808 provides that a licensed dentist can administer a flu vaccine to a patient who is at least 9 years old, can administer a vaccine that is listed in the CDC's recommended immunization schedule to a person between 11 and 18 years old who has a prescription from an authorized provider and, operating under a written protocol that is vaccine specific and meets criteria contained in Department of Health regulations, can administer a vaccine to an adult that is either listed in the CDC's recommended immunization schedule or that is recommended in the CDC's health information for international travel.

In each of these cases, before administering a vaccine, the bill requires the dentist to obtain from the patient, or in the case of a child the child's parent or guardian, a signed medical history and a signed consent form that clearly outlines the benefits and risks of the particular vaccine.

Senate Bill 808 also contains elaborate reporting requirements. A dentist administering a vaccine is required to report all vaccines administered to the State's ImmuNet program, is required to try to inform both the patient's authorized prescriber (in the case of a prescribed vaccine) and the patient's primary care provider of the administration of a vaccine.

In addition, the bill requires the dentist to enter relevant information about the vaccine in the patient's chart and to provide the patient with a vaccination card that contains all relevant information about the vaccine, including any post-vaccination instructions, a list of the possible side effects of the vaccine, instructions for addressing possible side effects, the dentist's after-hours personal contact information in the event of an emergency reaction and the name of the urgent care center closest to the site where the vaccination was administered.

Senate Bill 808 is being supported by the Maryland Department of Health, the Maryland Board of Dentistry, the Maryland Dental Association and the University Of Maryland School Of Dentistry.

Senate Bill 808 will help to improve vaccine distribution and allow for greater access to these vaccines. In passing this legislation Maryland will join other states such as Oregon, Illinois, Minnesota, and Georgia, which have already passed similar bills. COVID-19 has shown how important it is to have proper vaccine distribution, and by allowing our dentists to assist with this process we will provide greater access to healthcare for all Marylanders.

For these reasons, I hope that you will give Senate Bill 808 a favorable report.

2.26.2021 - SB808 - OPPOSE - Ausiello-Rosenthal.pd

Uploaded by: Ausiello-Rosenthal, Jennifer

Position: UNF

OPPOSE SB808 – Health Occupations – Licensed Dentists – Administration of Vaccines

Dear honorable members of the Education, Health, and Environmental Affairs Committee,
Thank you for serving our community. I am writing to strongly oppose SB808, Health Occupations-Licensed Dentists - Administration of Vaccines Act. I am opposed to this bill for the same reason I am opposed to SB736 that proposes pharmacists administer vaccines. Neither dentists nor pharmacists are trained to properly assess a child for risks and/or contraindications. In reviewing the other bills this legislative session, there are bills to expand the role of paramedics, dentists and pharmacists so that each of these respective roles can administer vaccines. It appears these bills serve only to increase revenue rather than actually solve any actual public health "problem." Vaccination rates in our state are incredibly high. Putting children at risk in order to increase profit for various sectors of the healthcare industry is unacceptable. Keep in mind that should an adverse event occur, those administering the vaccine are not liable, per the 1986 National Childhood Vaccine Injury Act. This is another irresponsible bill. Please vote against this bill. Thank you for your time.

Kindly,

Jenn Ausiello-Rosenthal

District 39

SB808-OPPOSE.pdf
Uploaded by: Butler, Jenna
Position: UNF

Chair Pinsky, Vice Chair Kagan, and members of the EHEA Committee,

I'm writing to strongly oppose SB 808 and urge the committee to decline moving this bill forward. Although this legislation has the intention of "helping with the pandemic," the reality of it in practice is far too expansive and permissive to be safe. We do not need limited, emergency measures to become permanent practice in Maryland at the expense of our children.

Is it truly appropriate for a child to visit the dentist for a medical procedure that should remain with their pediatrician? It is so important that we hold healthcare providers to reasonable scope of care, especially when it comes to our children. The childhood vaccination schedule is complicated and should be approached with the specific knowledge and intent of a specialist.

The only CLEAR benefit to this legislation would be to dentist offices' bottom line- did you know that flu shots bring in an estimated $20 in profit a pop? Meningitis B- $48 profit, HPV- $50 profit, and Hepatitis B $80 profit? There are other measures specifically designed to improve vaccination access during this time and there is truly no need for this legislation. When there are also CLEAR risks to the health of Marylanders and Maryland's children to be considered, this legislation cannot move forward just because it is economically favorable to one profession.

I am also deeply disturbed by the language in this legislation that suspends the training and education requirements in the event of a declared "emergency." We cannot leave caution behind in favor of speed- the potential for unintended consequences is far too great.

The question is not whether or not dentists **COULD** administer the vaccinations, it is if they **SHOULD**. I urge you to consider the strong opposition to this legislation.

Respectfully,

Jenna Butler
Annapolis, Maryland

Unfavorable SB808.pdf
Uploaded by: Carr, Christie
Position: UNF

February 26, 2021

Dear Education, Health, and Environmental Affairs Committee Members,

I am writing to request that you kindly **oppose** Senate Bill 808: Health Occupations – Licensed Dentist-Administration of Vaccines.

I am concerned about the number of bills that I have seen which attempt to broaden those who can administer childhood vaccinations. As a parent of a child with a complicated medical history, I would only wish for my children to be administered a vaccine by their pediatrician who has followed them since birth. I do not believe it is safe nor necessary to allow pharmacists or dentists to administer shots to children. When I take my child to the dentist, I want the dentist to be focused on oral health and dental care. The time is limited during these appointments. What training do dentists have in pediatric care that permits them to move into administering the vaccines on the recommended schedule? What happens if there is a serious side effect that occurs after the vaccination is administered?

It is my understanding that the goal of this legislation was to let dentists assist with administering vaccines for COVID for those that want one. However, nothing in this bill is written for this purpose. I would not be opposed to dentists assisting in administering vaccines for COVID to any adult that wanted one. However, I absolutely oppose dentists administering any vaccines to minors under the age of 18 years old.

I ask that you please oppose this unnecessary bill.

Sincerely,

Christie Carr

1210 Corbett Rd

Monkton, MD 21111

SB 0808.pdf
Uploaded by: Couch, Lindsay
Position: UNF

I strongly oppose SB0808. To allow dentists to administer vaccines is unethical. They are not trained in vaccination administration nor do they have the means to properly assess any medical concerns after the vaccine is administered should there be an adverse effect.

SB808_Oppose_LMDPAC.pdf
Uploaded by: Cusack, Sarah
Position: UNF

SB808: Health Occupations – Licensed Dentists – Administration of Vaccines
OPPOSE
Love Maryland PAC

Dear Chair Pinsky, Vice Chair Kagan, and Distinguished Members of the Education, Health, and Environmental Affairs Committee,

Our organization is concerned about a trend in bills that would allow a variety of providers to vaccinate children, even though these providers are not qualified to do so.

- Young children are not vaccinated like adults. They have a complicated "recommended" schedule by the CDC that requires an assessment to determine actual vaccine appropriateness. Issues such as allergies, diagnoses (autoimmunity, immune system dysfunction, immune system suppressing drugs), current health status, and previous adverse reactions to vaccinations are just some of the things that pediatricians consider before determining what vaccine a child should have in a visit. They do not go by a checklist. At well-visits, pediatricians perform a full physical examination and medical history prior to determining vaccine readiness. Dentists do not have this expertise.

- No one is liable if a dentist gives an inappropriate vaccine, or if they administer it incorrectly. The Federal 1986 National Childhood Vaccine Injury Act removed liability from vaccine makers as well as the provider that administers the vaccine

- The sponsor's office said that this bill is to address the Covid-19 pandemic. The bill should be amended to only include the Covid-19 vaccine. As it is, the bill includes all CDC recommended vaccines. There is no reason for these to be given in a dentist's office. What physician is going to say, "I recommend that your child receive the Gardasil vaccine. Here is a prescription. Go to your dentist to receive it."?

- Parents get very little time with their child's dentist as it is. Most children have a cleaning by a hygienist and just a few minutes with the dentist to hear their assessment and x-ray results and to discuss future dental work and consults to orthodontists and oral surgeons.

- We are concerned that this bill represents a "cash grab" by dentists who have had a difficult year financially because people did not come in for cleanings and appointments due to the pandemic.

We respectfully ask for an Unfavorable Report from the Committee.

Love Maryland PAC

Silver Spring, MD

2021 MNA SB 808 Senate Side.pdf
Uploaded by: Elliott, Robyn
Position: UNF

Committee: **Senate Education, Health, and Environmental Affairs Committee**

Bill Number: **SB 808: Health Occupations – Licensed Dentists – Administration of Vaccines**

Hearing Date: **March 2, 2021**

Position: **Oppose**

The Maryland Nurses Association (MNA) opposes *Senate Bill 808 – Licensed Dentists – Administration of Vaccines*. MNA believes that dentists have the education and training to administer vaccinations. There may be some circumstances, such as during the COVID-19 pandemic, where dentists can play an important public health role in making vaccinations more available. However, we are opposed to the bill for several reasons:

- Public health planning should guide decisions about expanding who administers vaccinations. We are aware of no state policy discussions about the role of dentists in vaccine administration beyond the pandemic; and

- There are many practical considerations about integrating vaccination administration into dental practices beyond the pandemic, including:
    - Storage and Potentially Wasted Vaccines: Vaccines must be stored in controlled environments (i.e. refrigerated at a certain temperature) and expire after a certain time period. Do dental offices have the storage for vaccines? And will dental offices have a sufficient volume of vaccine patients so that vaccines will not be wasted?

    - Syncing the timing of vaccinations with dental visits: Many vaccinations require multiple shots, and the follow-up shots must follow a certain schedule. It is unlikely that the booster shot schedule will align with regular dental visits. How will booster shots be coordinated?

Nurses support integrating somatic, behavioral health, and oral health care. Dentists are a critical part of the health care team. Expanding the role of dentists in vaccination administration is a worthwhile issue to explore. However, we cannot support this bill because there was no public health planning with other health care providers on the development of the bill. We ask for an unfavorable report. If we can provide any further information, please contact Suhani Chitalia at schitalia@policypartners.net

Oppose SB 808.pdf
Uploaded by: Hartman , Nicole
Position: UNF

Oppose SB 808

Dear Mr. Pinsky and committee,

As a mom, I take the relationship between my children's doctor, child, and myself very seriously. Their doctor knows my children and their medical history. Their dentist does not. I believe this bill will have some unintended harms to children...What if a child has an allergy to vaccine ingredients? What if a child has had a negative reaction to vaccines? The dentist doesn't know this information and rightfully so. After all, they went to dental school to become a dentist. Not a pediatrician. I take my children to the dentist to ensure good oral hygiene, not vaccines.

We know that medical error is already the third leading cause of death in the United States. Let's not do anything further to increase that statistic.

Thank you for your time in listening to the voices from this great state of Maryland!

All the best,

Nicole Hartman

SB808_Helms_OPP.pdf
Uploaded by: Helms, Jessica
Position: UNF

OPPOSE SB808
Health Occupations – Licensed Dentists – Administration of Vaccines

I am writing to oppose SB808 as it is unnecessary. Dentists don't need to be giving vaccinations. Seeing as a client would need to have a prescription, it is likely that they saw their doctor in person. That doctor could just as easily have given the vaccination in their office while the patient was present and likely would have if they thought it necessary. Dentists should be focused on teeth and not on vaccinations. Leave that to the pediatricians.

Thanks,
Jessica Helms
Capitol Heights, MD

VOTE_NO_SB_808.pdf
Uploaded by: Hibbert Nelson, Annette
Position: UNF

February 25, 2021

Annette Nelson
2603 Terrapin Rd.
Silver Spring, MD 20906
caravelloah@yahoo.com

Dear Respected Members of the Senate Education, Health and Environmental Affairs Committee,

I am writing to urge you to reject SB 808. There are several problems I see with this bill.

I don't understand why dentists would support this bill in the first place. Certainly it will help them have another service to offer and charge insurance companies for, but in the long run it will certainly hurt their practices. Kids are already hesitant to visit the dentist. If you add getting a vaccine to the experience that very well might result in even more adults afraid of the dentist and just don't go.

But more importantly, this opens the door for families to stop taking their kids to the pediatrician. It's hard to get pre-teens and teens into wellness visits, however it's an incredibly important visit for them. Pediatricians do so much more than just administer vaccines at those appointments. They look for abuse and neglect. They are a safe place for kids to bring up issues like birth control needs, metal health issues, questions they might have about their sexuality. Many times these visits are done without the parents so kids have the space to ask questions of a medical professional they have grown up going to and trusting. If suddenly they don't have to go to the pediatrician to get their routine vaccine, many parents might just stop taking them to the pediatrician. Why go to two places if you can just go to one? Yes, I do understand that parents still need a prescription from the doctor to get the vaccine at the dentist. Can't you just see parents pressuring doctors into just writing a script though? What pediatrician is going to say, "Thanks for coming in for your well visit today. Here's a script for getting your vaccine at the dentist." It just doesn't make any sense.

What problem is this bill trying to address? Certainly it's not just dentists having suffered this year from reduced appointments and services due to Covid restrictions? So if it's to help families, it seems like it would actually harm them in the long run. If you wanted to allow dentists to administer vaccines why not change it to adults. That might actually makes sense. Adults often rarely for yearly physicals but they are adults can do what they want. However, if they were able to go to a dentist and get their flu shot all in one visit that might help. Just keep the kids out of it. They need to go to their pediatricians.

Sincerely,

Annette Nelson

SB0808_UNF_MDAAP, MACHC_Health Occs - Licensed Den

Uploaded by: Kasemeyer, Pam

Position: UNF

TO: The Honorable Paul G. Pinsky, Chair
Members, Senate Education, Health, and Environmental Affairs Committee
The Honorable Chris West

FROM: Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman

DATE: March 2, 2021

RE: **OPPOSE** – Senate Bill 808 – *Health Occupations – Licensed Dentists – Administration of Vaccines*

On behalf of the Maryland Chapter of the American Academy of Pediatrics and the Mid-Atlantic Association of Community Health Centers, we submit this letter of **opposition** for Senate Bill 808.

Senate Bill 808 authorizes a licensed dentist to administer influenza vaccines to a patient who is at least 9 years old without a prescription from an authorized provider and to a child ages 11-18 with a prescription. It also authorizes dentists to administer vaccines listed in the CDCs recommended immunization schedule as well as international travel vaccines to adults.

While there is not opposition to considering how dentists could be appropriately incorporated into the permanent framework of vaccine administration, there has been no deliberative discussion involving dentists and other health care providers engaged in vaccine administration to define an appropriate framework. Senate Bill 808 simply duplicates the existing statutory framework for pharmacist administration. There should be a more thorough discussion of the appropriate framework for authorization before legislation is enacted.

It should be noted that Senate Bill 808 recognizes the importance of requiring a prescription from a pediatric provider for the administration of a vaccine, other than influenza, for children ages 11-18 and that administration should be prohibited for children under the age of 11 (age 9 for influenza). As noted in discussions related to expanding vaccine administration authority for children to pharmacists, the unintended consequences of fragmenting care for children outweighs the perceived benefit of expanding access – especially given that Maryland has one of the highest vaccination rates in the country.

The above-named organizations look forward to having a dialogue with the dental community on how they may be engaged in expanding access to vaccines through an appropriately structured authorization framework but do not believe that legislation should be enacted prior to such a dialogue. An unfavorable report is requested.

For more information call:
Pamela Metz Kasemeyer
J. Steven Wise
Danna L. Kauffman
410-244-7000

Please oppose SB0808.pdf
Uploaded by: McCullough, Karen
Position: UNF

Please oppose SB0808.

There is a reason why doctor's have specialized fields because they have specialized training. Pediatricians have specialized training to deal with children's issues including the vaccination schedule. They are aware of the child's full medical history and contraindications.

What training does a dentist have to deal with a child who has a bad reaction to a vaccine or to administer vaccines? And why stop there…why just dentist. How about chiropractors, orthopedic, my psychiatrists, my opthalmologists, etc.

Vaccines are not skittles and should not be treated as so. Vaccines caused serious health conditions which they have been harming children and the government keeps allowing this to happen without any civil liability from these pharmaceutical companies. Please don't tell me vaccinations are safe because the federal vaccine injury compensation program has paid over $5 BILLION to children and adults for injuries and DEATHS caused by vaccinations.

Vaccine makers and the healthcare providers who administer them bear zero liability for vaccine injuries and deaths. Vaccine makers have no incentive to make vaccines safe.

I'm not sure of the reason for this bill and I pray it is not for greed. Children should have access to safe, trained pediatric care and if that is the motive then come up with a bill that helps have more access to pediatricians not put a vaccine into an un -trained hand to put a bandaid on the issue.

I am a CARING AND LOVING PARENT and a registered voter and I will be watching this bill closely.

Thank you
Karen

Oppose SB808 2.26.21.pdf
Uploaded by: Montgomery, Megan
Position: UNF

Oppose SB808- Written Testimony by Megan Montgomery

Good Afternoon, I write to request that this committee vote against SB808. Giving dentists the ability to vaccinate children will harm children's total health care outcomes. When I take my child to the dentist, we are lucky if we get more than a couple minutes with our actual dentist. The hygienist does our cleanings, and then we briefly see the dentist. In that short amount of time, we need to discuss cavities, tooth and mouth health and development, talk about the future need for extractions, orthodontia and any other issues that arise during our visit. We DO NOT have time to talk about immunizations as well. Nor do I want to have my child vaccinated in such a small and non-private space. Dental offices typically have small open bays that work well for dental cleanings and procedures, but are not suitable for giving private health care or wrestling with little bodies through a series of vaccinations.

Pediatricians visits are centered around the health and wellness of the whole child, and their offices are set up to give immunizations as part of a total health care visit. That is where the immunization of children belongs- in the pediatrician's office where they have the time and set up for it.

Please don't vote against children by burdening a dental visit with vaccinations. It's bad for children.

Thank you,

Megan Montgomery

OPPOSE SB808_Pladna.pdf
Uploaded by: Pladna, Heather
Position: UNF

OPPOSE SB808

I fear that SB808 will act as a barrier between pediatricians and their patients as well as add a layer to the dentist/patient relationship that need not exist.

It is clear that the pandemic-frenzy has piqued the interest of healthcare professionals who aren't otherwise approved to administer vaccines. It is disturbing to me that dentists would be interested in exploiting fear in order to increase profits at the cost of their relationship with their minor-patients.

Dentists and child-patients already have an anxiety-ridden relationship in many cases. Children know that a trip to the dentist entails potentially uncomfortable oral procedures but to now have to also anticipate the anxiety and discomfort of vaccination, seems cruel. As superficial as this may seem, as a parent, it is important to me to foster a trusting relationship between my children and their healthcare providers. It would be difficult to explain to my child why someone who specializes in oral health is now interested in providing a vaccination that is unrelated to oral health. Would my child then be worried that the pediatrician might now insist on performing a thorough dental-cleaning? Let's not confuse roles. Specializations exist for a reason. Doctors are more than vaccine-mills and the doctor/patient relationship/history is necessary for proper vaccination-consideration and administration. Similarly, dentists are more than a peddling opportunity for vaccine manufacturers; allow them to focus on their specialty without muddying the waters.

Dental offices are already very busy with patients often scheduled back-to-back. The actual time with the dentist is quite abbreviated. Only several minutes during a routine-cleaning appointment are spent with the dentist face-to-face. How much longer will these appointments have to be to also include the necessary conversation that informed-consent requires to provide a vaccine to the patient? Do dentists have all the necessary information to vaccinate a patient? Vaccination is more than a simple shot-in-the-arm. Many parents have questions about the potential risks of the illness itself as well as the risks and benefits of the vaccine. For example, dentists are not equipped to talk with parents about how the influenza virus is communicated and what the potential consequences of declining the vaccine may be. Even if Dentists did have comprehensive training in virology, they simply do not have the time to have these conversations.

Are dentists equipped to discuss the potential risks of the vaccine itself and to advise patients on where to go if adverse effects occur? How would they explain to their patient that while they are considered qualified to dispense and administer a vaccine, they are not qualified to treat reactions related to said vaccine? It seems like a disconnect that someone who may have a reaction to a vaccine would be advised to then follow-up with a medical doctor when the dentist is the one who administered the vaccine in the first place. The patient would then have to seek out an appointment with a medical doctor who would have to be informed of when/where the vaccine took place and would likely need to consult with the dentist about what may have caused the adverse reaction. Why would we place this potential delay in treatment by confusing the role of the dentist?

Oppose SB808.pdf
Uploaded by: Rauhofer, Jennifer
Position: UNF

I am writing as a concerned parent who is opposed to this bill. Allowing dentists to vaccinate children is reckless as children's immunization schedules are complicated as compared to adults. They should only be receiving vaccinations from a trained medical professional who is aware of their history and health. Why are there so many bills attempting to let other professionals vaccinate children?

I urge you to pull this bill to protect children and allow parents to have a relationship with their pediatrician to get the best outcome for our children.

SB808_oppose_sharpe.pdf
Uploaded by: Sharpe, Julie
Position: UNF

SB808

I am opposed to this bill.

Dentists are very good at evaluating my kids' teeth, at helping with cavities, at monitoring needs for braces, and many other elements of dentistry I've yet to need or take advantage of.

But following the recommendations of the CDC vaccine schedule for childhood vaccines is not something I would want to be added to their responsibilities.

There is a benefit to being able to rely on expertise at the pediatrician. It is so good that we are able to have the relationship with the doctor that we do. The doctor has the kids' charts and knowledge of their histories and time to devote to a general health conversation.

Dentists do not have any of this.

Dentists are great with teeth. Let us not send children to the pediatrician for a cavity, and let us not send them to the dentist for a vaccine.

Thank you for voting no to this bill.

Sincerely,

Julie Sharpe
3980 Hunting Creek Rd
Huntingtown MD 20639

443-968-8149

SB808 Testimony.pdf
Uploaded by: Stoklosa, Margaret
Position: UNF

Dear Committee Members,

Please give an unfavorable report on SB808 - Health Occupations – Licensed Dentists – Administration of Vaccines.

Dentists are not trained to administer vaccinations. That is not in their purview, that is not what they studied, and they do not have the appropriate relationship with a child/parent (complete medical history) to administer an agent capable of altering the immune system. Vaccines are viral agents that if given inappropriately or at the wrong time, can have multiple health repercussions. Additionally, the CDC schedule is a “recommended” schedule, whose timeframes may need to be tweaked based upon physician assessment – dentists are not qualified to make this assessment.

I really would like my dentist focused on what they do best – making sure my oral health is up to par and fixing any issues in dental enamel. If they now focus on vaccines, the quality of their work will suffer and they could make mistakes that may result in enamel loss (which is not replaceable).

In general, I am concerned about the bills this session and the trend for other professions to administer vaccines. I am not sure what is driving this trend, however, I am concerned that it is driven by profits and greed. Vaccines are quite the profitable business, aren’t they?

Also, with this bill who will monitor for vaccine reactions? The dentist who is not easily reachable? Pediatricians and physicians, by virtue of their positions, are more contactable and are also trained to recognize and report reactions to VAERS. Dentists are not trained to recognize reactions and probably have no idea what VAERS is, which creates a concerning situation should a significant reaction occur. All downstream effects of this bill need to be considered.

Again, I ask for an unfavorable report on SB808. As representatives of the people it is your responsibility to protect constituents, especially from bills that undermine important relationships that protect an individual’s health.

Thank you,
Margaret Stoklosa
Gaithersburg, MD
Gosia2200@yahoo.com

Gardasil Chemical Cocktail 2020.pdf
Uploaded by: Tarsel, Emily
Position: UNF

Frontiers in Women's Health

Commentary

ISSN: 2398-2799

The expanding cocktail of harmful ingredients in human papillomavirus vaccines

Arthur E Brawer* and Deborah H Sullivan

Monmouth Medical Center, Long Branch, New Jersey 07740, USA

Vaccination-induced disorders are a genuine reality that continue to generate intense controversy. Although the majority of immunization recipients have little or no safety issues, that does not detract from the occurrences of multiple systemic diseases initiated by a wide variety of parenteral vaccine exposures. Over the past four decades case reports of chronic vaccination-induced disorders have generally segregated into two main categories: (a) autoimmune and autoinflammatory diseases; and (b) neuro-psychiatric diseases, characterized by overlapping clinical features of the various neurologic fatiguing syndromes [1-5]. Afflicted individuals in category "b" are typically Gardasil vaccine recipients. They manifest widespread generalized pain, fatigue, muscle weakness, and small fiber neuropathy, along with mood and sleep disturbances, lethargy, headaches, dizziness, vertigo, reduced alertness, tinnitus, hearing loss, motor neuron dysfunction, abnormal gait, adverse cardiovascular events (e.g., orthostatic fainting, postural tachycardia, other arrhythmias, heart block), gastrointestinal complaints (e.g., cramps, nausea, vomiting, diarrhoea), cognitive dysfunction (e.g., memory lapses, learning impairment), tremors, seizures, metabolic disturbances (e.g., menstrual irregularities), and even sudden death [3-9]. The published reports of category "b" phenomena begin after either Gardasil 4 and/or Gardasil 9 immunizations, regardless of whether any single individual had received one, two, or three separate parenteral doses designed to protect against human papillomavirus induced cancers [10-12]. Within category "b" there also exists considerable diversity regarding the types of clinical features manifested by any single patient, as well as considerable heterogeneity in their time to onset, severity and persistence. Complicating all of this is the lack of specific nomenclature for category "b" events, in part because multiple investigators have identified a variety of autoantibodies and cytokines in ailing Gardasil recipients, and others have grossly oversimplified disease features to resemble patterns seen in fibromyalgia, chronic fatigue syndrome, neuroinflammation, dysautonomia, postural orthostatic tachycardia syndrome, Gulf war illness, macrophage myofasciitis, small fiber neuropathy, and complex regional pain syndrome [9,13-18]. In essence, mechanisms of disease causation put forth by these researchers to account for category "b" events are superficial, overly simplistic, disjointed, and at times inherently contradictory [19,20]. All of these confounding factors have added considerable fuel to the Gardasil controversy, and questions continue to persist regarding definitive identification of those at risk for this bizarre syndrome.

How then can one implicate Gardasil 4 and 9 vaccines as the cause of such a profound multisystem illness? First and foremost, it is becoming increasingly apparent that Gardasil vaccines contain a cocktail of harmful chemicals capable of producing dozens of biochemical disruptions in the body [4,21]. Several of these chemicals are organosiloxanes (commonly known as silicones), silicon dioxide (commonly known as silica), and sorbitol. All three have recently been implicated as participants causing systemic toxicity in Gardasil recipients. Any autoimmune features in these scenarios have been relegated to secondary amplification loops that circuitously enhance the disorder once it is already underway [4,5]. As the list of known harmful substances present in Gardasil expands, multiple overlapping pathophysiologic disruptions of the body's biochemistry become more and more plausible. Perhaps the most glaring new revelation is the Identification of volatile organic compounds in the toluene and benzene families that persist in the finished Gardasil products [22]. Official chemical designations are phenylmethylsulfonyl fluoride (PMSF) and aminoethylbenzenesulfonyl fluoride (AEBSF) respectively. A synonym for PMSF is toluenesulfonyl fluoride. These two chemicals are used in the extraction process of the protein peptides that serve as the antigenic stimuli in Gardasil 4 and 9 vaccines. However, volatile organic compounds like toluene and benzene readily diffuse into organosiloxane polymers [23], and silicones are hidden toxic ingredients in Gardasil vaccines [4,5,21]. This, in turn, implies that purification of the protein peptides via inactivation of PMSF and AEBSF is incomplete, because these two compounds can be shielded by their absorption into silicones. Indeed, a recent independent chemical analysis of two Gardasil 9 vaccine vials confirms the presence of toluene and benzene compounds.

The side effects of toluene and benzene are numerous and include virtually all the adverse phenomena noted in category "b", as well as acidosis, chest tightness, and shortness of breath [24-26]. The reasons for these phenomena are multifactorial. Firstly, toluene compounds have been shown to cause dysfunction of cardiac voltage-gated sodium and calcium channels that are responsible for membrane depolarization and action potential conduction [27]. Since voltage-gated sodium channels are also abundant throughout the nervous system, channelopathies caused by toluene, in concert with previously described organosiloxane-induced channelopathies [5], provide a nasty adverse synergistic amplification loop. In addition, both toluene and benzene compounds have been shown to cause dysfunction of potassium channels in neurons and ovaries [28,29]. Consideration also needs to be given to any inherited channelopathies that are clinically innocuous under ordinary everyday conditions. These can become symptomatic following even small amounts of volatile organic compound exposures. Secondly, PMSF and AEBSF are serine protease inhibitors, and both inhibit the enzyme activity of acetylcholinesterase

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Received: October 12, 2020; **Accepted:** November 06, 2020; **Published:** November 10, 2020

[30,31]. As such, they cause overactivity of acetylcholine in any cells, tissues and organs where muscarinic, nicotinic and central neurotransmitter activities are necessary for normal physiologic functioning. Digestive enzymes originating from the pancreas are also serine proteases, and their enzymatic activities are equally negatively affected by these volatile organic compounds [30]. The protein precursor to brain derived neurotropic factor (BDNF) is cleaved by a serine protease to form mature BDNF. BDNF supports memory formation and maintenance, and mitigates against mood swings, stress, and fear [32]. When PMSF and AEBSF interfere with the formation of mature BDNF, neuro-psychiatric dysfunction is the expected result. Thirdly, PMSF is also a serine esterase inhibitor and can have a direct negative effects on the central nervous system by causing pathologic persistence of neuropeptides such as endorphins, enkephalins and substance P. Fourthly, toluene can cause dysfunction of central muscarinic receptors as well as adrenergic arrestin receptor complexes in every autonomic nervous system arena [33-35]. The peptide molecular structures of these receptors incorporates the matrix macromolecule chondroitin sulfate [36], and since organosiloxane degradation molecules can biointegrate into (and disrupt the function of) matrix macromolecules [4], receptor dysfunction caused by PMSF is another example of an adverse synergistic amplification loop. From the above discussion it is obvious that the side effects of PMSF and AEBSF can paradoxically be in competition with each other, creating conflicting havoc at any point in time via simultaneous biochemical blockades and biochemical excesses of many physiologic, neurologic and psychologic mediators and neurotransmitters. This paradoxical competition enhances all the other multifaceted biochemical disruptions attributable to previously described hidden Gardasil ingredients, in particular organosiloxane induced side effects of cholinergic receptor blockade, mitochondrial dysfunction, ion channel malfunction, chelation of dopamine in the brain, alteration of enzyme activities, and inappropriate mast cell degranulation [4,5,21].

PMSF can create additional biochemical and physiological havoc by virtue of its ability to inhibit protein phosphatases, enzymes that remove a phosphate group from a previously phosphorylated amino acid residue of a protein [37]. Phosphatases act in opposition to protein kinases and protein phosphorylases, the latter two being enzymes that catalyze the transfer of a phosphate group from ATP to amino acids on proteins. Phosphate addition and phosphate removal do not necessarily correspond to enzyme activation or enzyme inhibition. This sphere of metabolism is highly dynamic and plays crucial roles in an extraordinary range of nuclear and cytoplasmic functions, including (but not limited to): intracellular trafficking, control of telomere length, apoptosis, cell cycling, cell movement, gene transcription and translation, learning and memory, signal transduction, blood glucose levels, and neuronal activity.

PMSF and AEBSF are capable of modifying human proteins by changing their isoform profiles [38,39]. An isoform is two or more functionally comparable proteins that have similar but not identical amino acid sequences. Their amino acid sequences can be encoded by different RNA transcripts from the same gene, a process that can be generated by these two volatile organic compounds because they have been shown to alter transcription regulators [40]. In the case where isoform proteins function as enzymes, these companions generate biologic diversity in their tasks and often perform their functions at different speeds. This, in turn, can alter (and even reduce) metabolic and enzyme efficiency. The field of metabolomics encompasses a comprehensive analysis of molecular compounds, and essentially analyses changes in the body's metabolism by looking at changes in substrates and metabolic products. In several of the neurologic fatiguing syndromes, especially chronic fatigue syndrome/myalgic encephalomyelitis, metabolomic alterations are legion [41,42]. Similar metabolic alterations can result from adverse isoform effects of PMSF and AEBSF. In addition, isoform enhancement caused by volatile organic compounds is capable of augmenting virtually any of the toxic side effects previously discussed, particularly disturbances of ion channel protein function.

Isoforms are also capable of triggering the production of autoantibodies by nature of their varied antigenic amino acid sequences and altered configurations. As previously mentioned, autoantibodies of various types have been identified in ailing recipients following human papillomavirus immunization, including antibodies to adrenergic and muscarinic receptors. These complement the varied mechanisms of autoantibody production caused by the hidden organosiloxanes [2,4,5]. But do these autoantibodies account for the wide variety of clinical phenomena manifested by Gardasil victims? Such diverse phenomena imply that multiple physiologic processes encompassing afferent fibres, efferent fibres, dorsal root ganglia, autonomic tissues, ion channels, and central nervous system are being rapidly compromised. When combined with all the other heterogeneous clinical features that, in the aggregate, are also often of rapid onset in these patients, it seems unlikely that Gardasil-induced systemic disease states are initiated by autoimmune and autoinflammatory events. Although the production of autoantibodies are indeed plausible occurrences after Gardasil immunization, they most likely arise as delayed overlapping secondary amplification loops that then augment and perpetuate any clinical features once the disease process is already underway. Autoreactive and autoantibody presence would not be unique to Gardasil-induced illness, because individuals suffering from chemical exposure, other serious conditions and infections, including SARS-Cov-2, have been noted to develop a variety of autoantibodies [5,43-48].

Why doesn't everyone vaccinated with Gardasil become ill? Part of the answer appears to be rooted in one's liver, which is the primary site of biotransformation of endogenous substrates, drugs and chemicals via the cytochrome P450 superfamily system of enzymes. The genes that code for these enzymes exhibit a high number of polymorphisms. As an example, the cytochrome P450-2D6 (CYP2D6) gene is responsible for the metabolism of many drugs and xenobiotics (chemical substances foreign to animal life). There are more than 130 inherited single nucleotide polymorphisms identified in one or both alleles of the CYP2D6 gene, some of which can even create missense mutations in either allele [49,50]. Thus, different versions of the same gene can confer various levels of functional enzyme status in different patients, ranging from ultra-rapid to poor to absent. Benzene is primarily metabolized by CYP2D6 and CYP2E1. As for toluene, the initial primary route of metabolism is by hydroxylation to benzyl alcohol by five members of the P450 family: CYP2E1, CYP1A2, CYP2B6, CYP1A1, and CYP2C8. A researcher has recently investigated two dozen Gardasil recipients with category "b" features, and allelic missense is present in at least three of these six genes in 100 percent of the cohort (unpublished data). The sickest patients manifest allelic missense in four or more of these six genes. This implies that the metabolism of PMSF and AEBSF in these patients is either significantly compromised or absent altogether. However, it should be noted that the entire family of P450 genes responsible for the metabolism of endogenous and exogenous compounds are not strictly separated from each other. It is therefore no surprise that multiple other P450 genes can code for enzymes that

use xenobiotics as substrates, including CYP2A6, CYP2A13, CYP2C9, CYP2C18, CYP2C19, CYP2F1, CYP3A4, CYP3A5, CYP3A7, and CYP3A43. It seems plausible that Gardasil recipients who are at risk for systemic toxicity lack the ability to properly confront the presence of parenterally administered PMSF and AEBSF in a timely manner. When such events are coupled with all the other hidden toxic Gardasil vaccine ingredients, a pathophysiologic mission impossible is initiated. This simultaneously clarifies the multiple confounding factors inherent to the Gardasil controversy, including the vulnerable population at risk and the subsequent evolution of autoantibodies. Other confounding factors for P450 enzyme suppression, such as alcohol consumption, cannabinoid use, estrogen use, and prescription drugs have been properly evaluated and excluded in the compromised Gardasil cohort. On a final note, it should be recognized that the antigenic portions of the Gardasil vaccine itself, via cytokine induction, can suppress P450 enzyme activities against a variety of chemicals and drugs [51]. Thus, in the presence of multiple defective P450 genes, even the beneficial portions of the Gardasil vaccine can circuitously enhance its own toxicity.

In conclusion, human papillomavirus vaccine-induced systemic illness is a genuinely novel disorder that likely encompasses dozens of biochemical and physiological disruptions orchestrated by the presence of multiple hidden toxic vaccine ingredients. The populations at risk for Gardasil-induced adverse events are not likely to exhibit autoimmune diatheses, but they probably exhibit overlapping indigenous risk factors that markedly facilitate acute chemical poisoning. These risk factors, in conjunction with all the hidden toxic vaccine ingredients in Gardasil, also elicit delayed secondary autoreactive amplification loops which, in turn, become capable of augmenting and sustaining the initial biochemical and physiological disruptions once they are already underway. Researchers investigating Gardasil-induced disease states should consider focusing their primary investigations towards identifying indigenous risk factors that logically correlate with chemically related adverse events.

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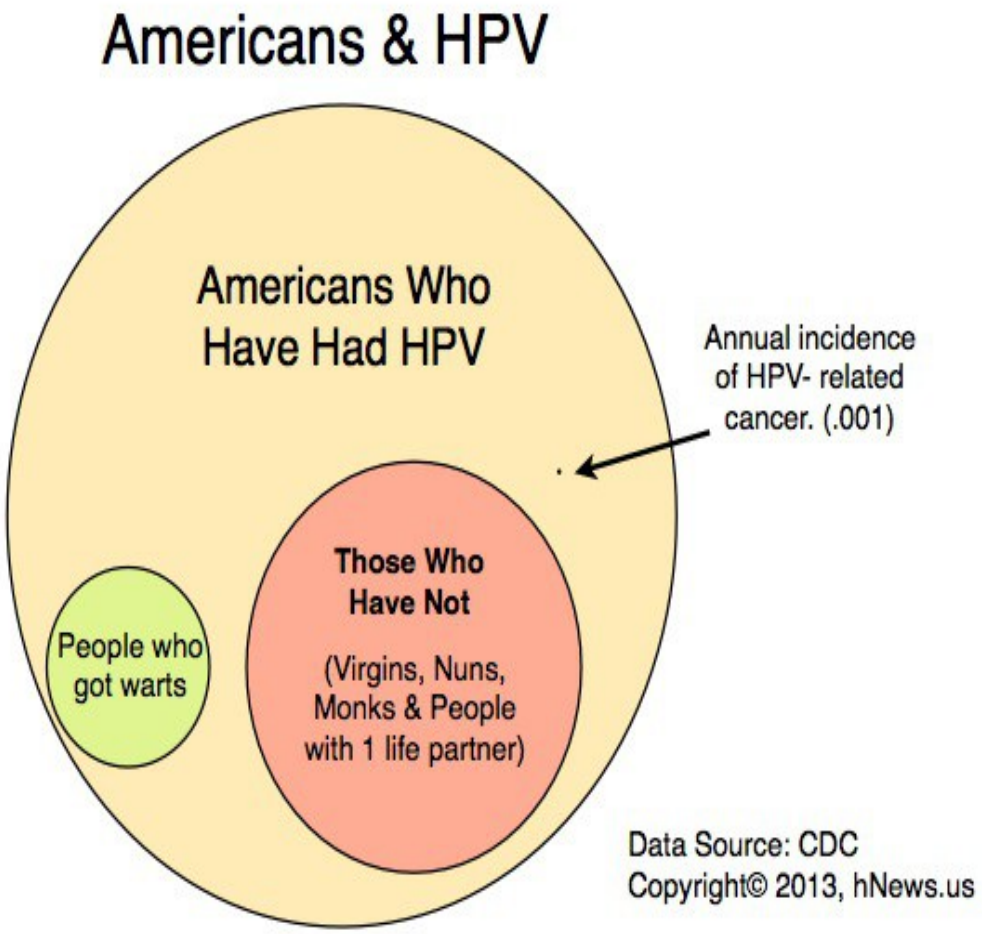
Americans & HPV
Americans Who Have Had HPV
Annual incidence of HPV- related cancer. (.001)
Those Who Have Not
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THEME - ETHICAL AND LEGAL CHALLENGES OF VACCINES AND VACCINATION

Lessons learnt in Japan from adverse reactions to the HPV vaccine: a medical ethics perspective

HIROKUNI BEPPU, MASUMI MINAGUCHI, KIYOSHI UCHIDE, KUNIHIKO KUMAMOTO, MASATO SEKIGUCHI, YUKARI YAJU

Abstract

The human papillomavirus (HPV) vaccine has been linked to a number of serious adverse reactions. The range of symptoms is diverse and they develop in a multi-layered manner over an extended period of time. The argument for the safety and effectiveness of the HPV vaccine overlooks the following flaws: (i) no consideration is given to the genetic basis of autoimmune diseases, and arguments that do not take this into account cannot assure the safety of the vaccine; (ii) the immune evasion mechanisms of HPV, which require the HPV vaccine to maintain an extraordinarily high antibody level for a long period of time for it to be effective, are disregarded; and (iii) the limitations of effectiveness of the vaccine. We also discuss various issues that came up in the course of developing, promoting and distributing the vaccine, as well as the pitfalls encountered in monitoring adverse events and epidemiological verification.

Introduction

In this paper, we review the adverse reactions following human papilloma virus (HPV) vaccination in Japan, and the measures taken by the Ministry of Health, Labour and Welfare (MHLW) (1) to withdraw active recommendation of the vaccine. These measures triggered domestic and international controversy. We also discuss various problems that occurred while developing, promoting and distributing the vaccine; the pitfalls encountered in monitoring adverse events and epidemiological verification; and the influence of big pharma on healthcare policy and research.

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To cite: Beppu H, Minaguchi M, Uchide K, Kumamoto K, Sekiguchi M, Yaju Y. Lessons learnt in Japan from adverse reactions to the HPV vaccine: a medical ethics perspective. *Indian J Med Ethics*. 2017 Apr-Jun;2(2)NS: 82-8.

I. Overview of the HPV vaccine issue in Japan

HPV vaccines were approved later in Japan than in the western countries (October 2009 for Cervarix, and July 2011 for Gardasil). The vaccination rate was initially low. However, after a campaign for the promotion of the vaccine, which led to government subsidisation of the cost of the vaccine in November 2010, the vaccination rate increased exponentially. This was followed by an unexpected increase in reports of adverse events (AEs). Importantly, these vaccines gave rise to a large number of serious AEs. Table 1 shows the number of reports of serious AEs/adverse drug reactions (ADRs), defined according to the ICH E2A guidelines (2), submitted with respect to HPV vaccines by vaccine manufacturers and medical professionals at the end of February 2016 (3). These numbers far exceed those for other vaccines, even if one allows for the probability that vigilance would be higher for a newly introduced vaccine than an older, time-tested one (4,5) (Fig. 1). As these data have been compiled from voluntary reports, the actual incidence of AEs may well be far higher (6,7).

Table 1
Reports of serious AEs/ADRs of HPV vaccines in Japan (3)

Vaccines	Total dose*	Total number of inoculated persons*	Serious AE/ADR reports	
			From MAH	From medical institutes
Cervarix	6,998,266	2,590,000	835	448
Gardasil	1,924,121	800,000	124	165

**Estimated from sales data*

***Note**: AE: adverse event; ADR: adverse drug reaction; MAH: marketing authorisation holder*

***Observation period**: December 2009–February 2016 (Cervarix), August 2011–February2016 (Gardasil)*

Other key features of the ADRs reported with HPV vaccines are the diversity of the symptoms and their development in a multi-layered manner over an extended period of time. The ADRs include complex, multi-system symptoms, such as seizures; disturbance of consciousness; systemic pain, including headache, myalgia, arthralgia, back pain and other pain; motor dysfunction, such as paralysis, muscular weakness, exhaustion and involuntary movements; numbness and sensory disturbances; autonomic symptoms, including dizziness, hypotension, tachycardia, nausea, vomiting and diarrhoea; respiratory dysfunction, including dyspnoea and

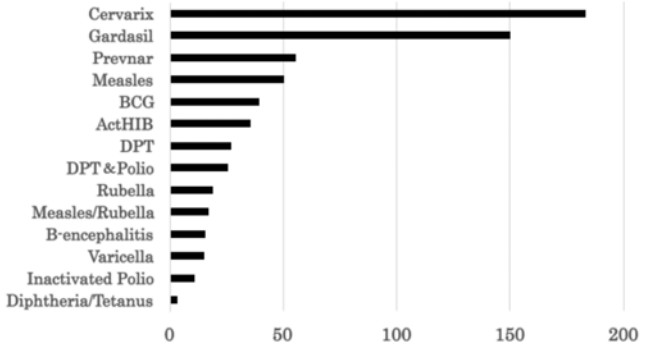

Fig. 1: Severe ADRs from HPV vaccines and other vaccines in Japan.
Data sourced from the national adverse events following immunisation (AEFI) registry in 2013–2016. (ADRs/10^6 inoculations)(4,5)
BCG: Bacillus Calmette–Guerin; DPT: diphtheria–pertussis–tetanus

asthma; endocrine disorders, such as menstrual disorder and hypermenorrhoea; hypersensitivity to light and sound; psychological symptoms, such as anxiety, frustration, hallucinations and overeating; higher brain dysfunction and cognitive impairments, including memory impairment, disorientation and loss of concentration; and sleep disorders, including hypersomnia and sudden sleep attacks. In some cases, these symptoms impair learning and result in extreme fatigue and decreased motivation, having a negative impact on everyday life (8–11). The situation in Japan is similar to that in other countries which have also reported a specific cluster of serious and complex symptoms that develop across multiple body systems over an extended period of time (12,13).

The reason why HPV vaccines cause these characteristic adverse effects remains to be studied in the future, but one of the most plausible explanations is that these vaccines are designed to maintain an extremely high antibody titre over a long period of time. Since prolonged inflammatory reactions associated with infection are known to cause autoimmune diseases and worsening of autoimmune reactions (14), long-time antigen stimulation with HPV vaccines might also induce complex autoimmune reactions via a mechanism similar to that seen with prolonged infection.

Individuals who experienced ADRs following HPV vaccination established a voluntary liaison organisation to facilitate communication with others who also experienced ADRs in Japan. When these ADRs were reported in the mass media, HPV vaccination became a major social issue. In response to the negative press surrounding HPV vaccination, the MHLW withdrew its active recommendation in June 2013 on the grounds of "an undeniable causal relationship between persistent pain and the vaccination"(1). As a result, the inoculation rate for the vaccine decreased rapidly [from 80% at its peak to less than 1% at present (15)]. In response to this change, proponents of the HPV vaccine initiated a push-back campaign and began actively lobbying the government.

On January 20, 2014, the expert advisory committee established by the MHLW (16) presented the view that the diverse pain and motor dysfunctions experienced by many individuals after HPV vaccination comprised psychosomatic reactions to anxiety or stimulatory pain caused by needle injection, and were not due to any components of the vaccine itself. However, doctors and researchers who examined patients with post-vaccination symptoms arrived at a completely different conclusion, highlighting both the characteristic symptoms and course, which are difficult to explain as psychosomatic reactions (9–11).

Thus, the safety of the HPV vaccine remains far from certain in Japan, justifying the public's strong distrust. Recognising the potentially negative influence of these events on public opinion in other countries, pharmaceutical companies initiated a counter-intervention strategy through public and private organisations, such as the World Health Organisation(WHO). The Global Advisory Committee on Vaccine Safety (GACVS), one of the WHO's advisory committees, claimed it had "not found any safety issue that would alter its recommendations for the use of the vaccine" and criticised the MHLW's decision to withdraw active recommendation (17).

Despite these obstacles, in July 2016, a victims' group filed a multi-plaintiff lawsuit in the district courts of Tokyo, Nagoya, Osaka and Fukuoka against the Japanese government and the two pharmaceutical companies that had produced these vaccines. Furthermore, in December of the same year, additional victims joined the multi-plaintiff lawsuit, bringing the total number of plaintiffs to 119 (18).

So far, we have reviewed the adverse reactions to HPV vaccines and the measures taken by the MHLW in Japan that provoked controversy both in Japan and abroad. In the next section, we discuss the safety and efficacy of the HPV vaccines promoted by the WHO and other organisations, and identify a flaw in the basis of their arguments in favour of the vaccines.

II. The problem with the HPV vaccine: refuting the GACVS statement (19)

a. Safety issues

Investigation by the MHLW

Regarding Japan, the GACVS statement (17) says that "review of clinical data by the national expert committee led to a conclusion that symptoms were not related to the vaccine". However, there are major problems with the expert committee's investigation (16).

The most serious problem is that very few members of the committee actually examined patients with post-vaccination symptoms. The committee's investigation focused exclusively on pain and motor dysfunction, and ignored many other diverse symptoms that have been observed. Further, cases in which adverse events occurred more than a month after vaccination were excluded from consideration on the ground that most adverse effects of vaccines occur within one month of vaccination. However, subsequent studies have clarified that symptoms commonly appear even after a considerable period of time has elapsed since vaccination (9–11).

The methods used for determining psychosomatic reactions to be the cause of symptoms are also open to question (16). The expert advisory committee proposed four hypotheses regarding the pathophysiology of post-vaccination symptoms: (i) neurological disorder, (ii) intoxication, (iii) immunological reaction, and (iv) psychosomatic reaction. Those cases which do not conform to the committee's criteria for (i)–(iii) were regarded as having no causal relationship with the HPV vaccine. However, since the definition of the psychosomatic response is ambiguous and the diagnosis is exclusively made by the subjective judgement of the doctor, many cases are diagnosed as psychosomatic reactions.

Support for the expert advisory committee's conclusion is far from universal. Doctors and researchers who actually examined patients with post-vaccination symptoms pointed out that it is difficult to explain all symptoms as psychosomatic reactions on the basis of the results of experiments and case reports (8–11, 20–22). Prior to investigating HPV vaccine-associated neuro-immunopathy (HANS), a new disease concept proposed by Nishioka (22),Yokota et al excluded from their survey all individuals who exhibited any physical/psychological abnormality before the vaccination (9). Thus, the survey design further strengthened the conclusion that the psychosomatic response could not account for the majority of the AEs of the HPV vaccine, as claimed by the committee.

Further, as 11 of the 15 members of the expert advisory committee have conflicts of interest with vaccine manufacturers, the public is justified in requesting that a more diverse range of scientists reviews the relevant data (23). Thus, the safety of the HPV vaccine remains far from certain in Japan, justifying the public's strong concerns. Outside Japan, Jefferson et al (24) and Gøtzsche et al (25) also expressed concern about the nature and quality of regulation of the HPV vaccine by the European Medicine Agency.

Criticism of the evidence for safety mentioned in the GACVS statement

Regarding the safety of the HPV vaccine, the GACVS claimed in its statement that it had not found any safety issues warranting an alteration in its recommendations for the use of the vaccine, and criticised Japan for stopping the active promotion of HPV vaccination (17). However, the studies (26–31) cited by the GACVS as evidence for the vaccine's safety raise the following fundamental questions.

i) Genetic basis of autoimmunity

Among the pathophysiological mechanisms related to adverse reactions after vaccination, the involvement of autoimmunity is one of the most probable. The various mechanisms suggested with regard to autoimmune diseases include: molecular mimicry (32), in which a foreign antigen shares structural similarities with self-antigen; the disruption of essential mechanisms in central and peripheral immune tolerance (33); and human endogenous retroviruses genes producing functional proteins or developing antibodies against the individual's own proteins (34).

Although the aetiology has not been fully elucidated, most autoimmune diseases are complex polygenic conditions, in which the affected individual inherits multiple genetic polymorphisms that contribute to disease susceptibility, and these genes interact with environmental factors to cause the disease. It is a well-known fact that some human leucocyte antigen alleles occur at a higher frequency in patients with certain autoimmune diseases than in the general population (35).

At present, what is claimed to be the primary evidence for the safety of the HPV vaccine is that there is no statistically significant difference in the incidence of autoimmune diseases among vaccinated females and unvaccinated females or the general population. However, since the proportion of genetically susceptible people in the general population is very small and limited, simple comparisons of the incidence of autoimmune diseases between those who have been vaccinated and a control (unvaccinated) group are likely to show no significant difference. Arguments that do not take this into account cannot assure the safety of the vaccine. The baseline prevalence of many autoimmune diseases is relatively low. Thus, careful large-scale post-marketing surveillance that takes into account the immunological characteristics of individual patients is required to scientifically verify the relationship between vaccination and autoimmune diseases (36).

ii) Coding and the loss of important information

In drug regulatory agencies and the pharmaceutical industry, all AEs in a patient's medical record are coded for computer processing and thus, details contained in the raw data are "lost". As a result, the clinical significance and extent of drug risk are masked(37,38). This process results in a kind of circular reasoning, in which post-vaccination symptoms are isolated and analysed retrospectively within the framework of the existing disease concepts, instead of being viewed comprehensively.

iii) Paradigm shift

HPV is equipped with various immune evasion mechanisms, which could cause the immune system to become more tolerant to the infection, creating a microenvironment susceptible to further infection and facilitating the progression of cervical intraepithelial neoplasia (CIN). To counteract these immune evasion mechanisms, the HPV vaccine is designed to maintain an extraordinarily high level of antibodies for more than a decade (39, 40). This moves the HPV vaccine out of the paradigm of "vaccine" as it is conventionally understood. These unique characteristics of the HPV vaccine make it essential to conduct a more thorough evaluation of its safety.

b. Effectiveness

While the GACVS statement claims that "the impact of HPV vaccines on HPV-related clinical outcomes, including pre-cancerous lesions, is well established", in actuality, the effectiveness of the HPV vaccine is quite limited, as discussed below.

First, the only verified effect of the HPV vaccine is a preventive effect on pre-cancerous lesions (specifically CIN); the preventive effect on cervical cancer itself has not been established. The effects of the vaccines currently approved in Japan (Cervarix and Gardasil) on pre-cancerous lesions have been demonstrated only in the cases of HPV 16 and 18, which, according to the most reliable studies, represent only 50% of cervical cancer cases in Japan (41).

Further, 10% or fewer cases of high-risk HPV infection result in persistent infection that can cause cancer, while the large majority of any pre-cancerous lesions (CIN) that do develop resolve before becoming cancerous (42, 43). Therefore, only 0.15% of individuals infected with high-risk HPV develop (invasive) cancer (44, 45). Even if cancer develops, regular check-ups can help to detect it at an early stage and appropriate treatment (surgery, radiation and drug therapy) saves many lives. On the basis of these facts, the promotion of educational activity that emphasises the importance of screening and early detection, as well as the creation of an environment in which women feel more comfortable undergoing Pap testing, would be far more effective at preventing cervical cancer than would pressuring teenage girls to receive the existing HPV vaccination, with all its problems.

The proponents of the HPV vaccines claim that they are 98%–100% effective in preventing cervical cancer. In reality, however, the absolute risk reduction (ARR) provided by HPV vaccines is, at most, 0.1%–0.7%, on the basis of calculations using the existing data (46). Further, this indicates only the reduction in the risk of developing pre-cancerous lesions, while the risk of developing cervical cancer remains unknown.

The promotion of screening for cervical cancer is another important measure against cervical cancer. For a long time now, attention has been drawn to the low screening rate for cervical cancer in Japan compared to the western countries. In particular, young women with no experience of pregnancy are reluctant to undergo gynaecological examinations in Japan. Access to examinations by female doctors and an acceptance of self-sampling would undoubtedly increase the screening rates. In fact, the promotion of screening for cervical cancer significantly reduced the age-adjusted incidence of invasive cervical cancer in the UK (47).

III. Structural flaws: an ethics viewpoint

In the previous sections, we discussed various issues regarding the safety and effectiveness of the HPV vaccine. It is now appropriate to ask how such questionable vaccines have come into widespread use. The answer, at least with respect to Japan, can be found in a structural flaw, combined specifically with the following factors: (i) aggressive promotion by the pharmaceutical industry, (ii) trade negotiations by economic superpowers, and (iii) contemporary medicine, which is characterised by overconfidence in technology and a lack of humility with respect to listening to patients' complaints.

a. Immunisation Act and HPV vaccine promotion by manufacturers

Following the enactment of the Immunisation Act in Japan in 1948, numerous lawsuits were filed in response to vaccine-related injuries. This resulted in the establishment of a compensation system for victims and the amendment of the relevant laws and regulations. At present, vaccines are divided into three categories, as shown in Table 2(48).

According to the definitions in the Act, a vaccine for individual protection, such as the HPV vaccine, should be classified as an "optional" vaccination, which is solely the individual's choice. However, due to lobbying activities, the HPV vaccine was approved as a vaccine to be administered at public expense, and was included in the category "Routine vaccination A". Since it was recommended by the government, individuals felt obligated to receive the HPV vaccine.

The Japanese Expert Board for the Eradication of Cervical Cancer (49), one of the most powerful lobbying organisations in Japan, was founded in November 2008, around the time the HPV vaccine was being reviewed for approval. The executive members of various medical academic societies joined this group and exerted considerable influence on the legislative process, as well as on public administration and the shaping of public opinion.

Table 2
Vaccination and legal categorisation

Category	Responsibility of individual	Vaccination
Routine vaccination A	Duty to make effort to receive vaccination	Hib, pneumococcal, BCG, diphtheria, pertussis, tetanus, polio, measles, rubella, varicella, HPV, HB, Japanese Encephalitis
Routine vaccination B	No particular social duty	Influenza (for elderly), pneumococcal
Optional vaccination	Discretion of individual	Pneumococcal (for adults), rotavirus,etc.

According to information obtained by Medwatcher Japan(50) under the *Transparency Guideline for the Relation between Corporate Activities and Medical Institutions* (51) of the Japan Pharmaceutical Manufacturers Association, the funds received by the Expert Board from vaccine manufacturers amounted to ¥73,500,000 (¥35,000,000 in 2012 and ¥38,500,000 in 2013). In addition, the secretary of the Expert Board was found to have been working at GlaxoSmithKline Co. as the Director of Marketing for vaccines for up to eight months prior to the launch of Cervarix. These facts strongly suggest that the activity of the Expert Board was not altruistic, but was actually disguised promotion(52).

b. Pressure from outside Japan

The promotion of the HPV vaccine during Japan–US trade negotiationshas also created pressure on Japan to adopt the vaccine. For many years, the promotion of vaccination has been

one of the most pressing requirements in trade negotiations with the US, Japan's most important trading partner (53, 54). The Center for Strategic and International Studies, a civilian think tank that is part of the US military–industrial complex, criticised the indecisiveness of Japan's government in reports issued in May 2014 and April 2015, reflecting the irritation of US industries (55,56).

c. Medical professionals forgetting their role

Basic defects inherent in the medical community underlie the issue of the HPV vaccine. In 2004, Sheldon Krimsky pointed out the increasing influence of commercialism in academic science and biomedical research in his book, *Science in the private interest* (57). He wrote, "…the mix of science and commerce continues to erode the ethical standards of research and diminish public confidence in its results. "In the 13 years since the publication of the book, his warning has become a reality everywhere in the world, not only in the USA. Originally, public health and pharmaco-epidemiology were the scientific fields that aimed to protect the health of individual patients and the public. However, the current reality is very far from the ideal.

Science is now misused to protect the interests of the pharmaceutical industry, and has been used to deny the causal relationship between the drug and its adverse reactions. Many researchers and experts are attempting to exclude inconvenient truths from consideration. "The taxonomy of diseases represents the nearest science has got to nature, but it remains a theoretical construct. It is the theory that should be discounted when the patient's symptoms refuse to fit, not the patient's account of the reality of their experience."(58, 59) This means that doctors must be more humble and scientifically honest. Today's diagnostics and therapeutics were created by listening to patients' voices and conducting careful examinations. It is irresponsible to dismiss a patient's complaint as a psychogenic reaction or a general phenomenon among young women without conducting a thorough examination.

IV. Considerations for solving problems

As described in section III, the introduction of HPV vaccination in Japan was promoted with an emphasis on commercial interests rather than as a public health need. This situation is not unique to Japan and has also been observed in other countries. In Australia, for example, despite the considerable doubts of the Pharmaceutical Benefits Advisory Committee about the Gardasil vaccine, the committee's decision to reject the addition of Gardasil to the national vaccination schedule was hurriedly overturned, following political interference and lobbying by other vested interests (60).In the USA, Merck & Co, Inc promoted legislation to mandate HPV vaccination for school attendance by serving as an information resource, lobbying legislators, drafting legislation, mobilising female legislators and physicians' organisations, conducting consumer marketing campaigns, and filling gaps in access to the vaccine. Legislators relied heavily on Merck for scientific information (61).The responsibility to prove the efficacy and safety of a vaccine lies with the pharmaceutical companies, and the government is expected to monitor and guide these efforts. The current situation in which commercial interests drive government policy must be corrected from a medical ethics perspective.

At present, Japan is one of the few countries in which the active recommendation of HPV vaccination has been temporarily stopped; the regulatory authorities in other countries have not changed their policies. Although various groups of victims of vaccination have collaborated on wide-ranging activities in these countries, the regulatory authorities have not yet admitted the causal relationship between the vaccines and the victims' health injuries.

The Japanese government's decision to stop actively recommending HPV vaccination has, to an extent, encouraged regulators and patients in other countries to question the value of HPV vaccination. Japan's efforts to stop active recommendation might have been successful because of its historical background of cases of environmental pollution and drug-induced suffering (Minamata disease, thalidomide, SMON, dura mater graft-associated Creutzfeldt–Jakob disease, HIV transmitted by contaminated blood products, etc), which occurred during the post-war period of rapid economic growth. In the multi-plaintiff suits that followed the instances of environmental pollution and drug-induced suffering, the plaintiff groups sought not only compensation for damages, but also institutional reform and revisions to the law to prevent the repetition of the same mistakes (62).

This historical background has created a situation in which the mass media and regulators cannot easily ignore the victims' complaints about the side-effects of new vaccines. It is here that we may find a clue on how to solve this problem. It is necessary to enhance transparency at every step of the approval process for pharmaceutical products, from new-drug development to post-marketing surveillance. At the same time, it is crucial to strengthen the management of conflicts of interest, and develop a system by which citizens can participate directly and have a voice in the planning of public health policy(63–65).

Conflict of interest

All the authors are members of Medwatcher Japan. Masumi Minaguchi and Masato Sekiguchi are Lawyers for the plaintiffs in the HPV vaccination lawsuits.

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Identifying ethical issues in the development of vaccines and in vaccination

VEENA JOHARI

Abstract:

Vaccines are a widely accepted public health intervention. They are also a profitable tool for pharmaceutical companies manufacturing vaccines. There are many vaccines in the pipeline, for various diseases, or as combination vaccines for several diseases. However, there is also a growing concern about vaccines and the manner in which they are developed and approved by the authorities. Approvals are fast tracked and adverse events and serious adverse events following vaccination are seldom reported once the vaccine gets its marketing approval. Thus, vaccines have been clouded with many controversies and their use as a public health tool to prevent diseases is constantly under challenge.

Public health and human rights have an intrinsic link, and any public health programme can be successful if the rights of people are respected, and upheld. A routine or compulsory vaccine programme tends to ignore rights of people that augment the legal and ethical issues relating to vaccinations. This article aims to identify the legal and ethical issues in the development of vaccines and in vaccination processes.

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To cite: Johari V. Identifying ethical issues in the development of vaccines and in vaccination. *Indian J Med Ethics*. 2017 Apr-Jun; 2(2) NS: 88-93.

HPV vac symposium-incentives.pdf
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Physician Incentives

- Competition
- Wine
- Quality Bonus Structure

ORLANDO HEALTH

testimony for 2021 -SB 808 oppose.pdf
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Position: UNF

Emily Tarsell, LCPC, LCPAT

2314 Benson Mill Road
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Oppose SB 808

March 2, 2021

Good afternoon Chair, Vice Chair and Senators,

I am Emily Tarsell and I'm here on behalf of Health Choice Maryland to oppose to SB 808. Dentists among others are seizing the pandemic moment to expand revenue sources by seeking authorization to broadly vaccinate.The American Dental Association has sponsored an essay contest titled,"Why your dentist wants you to get the hpv vaccine." [1] One hidden agenda of this bill is to allow dentists to give the **lucrative** HPV vaccine, Gardasil 9, apparently without parental consent. The FDA recently approved Gardasil 9 to allegedly prevent oropharyngeal (oral/throat) cancer even though there is no evidence it would do so.

HPV related cancers are extremely low in the US (see attached charts) especially in the young and are associated with other risk factors like smoking. But if this bill passes, dentists will hype the threat of oral/throat cancers especially to youth (like they did for cervical cancer) and try to scare them into vaccinating.The truth is the real serious risk is the vaccine itself. Adverse outcomes from the vaccine are high - 3x great than all other vaccines combined (see attached chart), with more than 10,000 seriously injured youth and 525 deaths, including the confirmed Gardasil-induced death of my 21 yo daughter 12 years ago.

A recent peer reviewed paper titled "The expanding cocktail of harmful ingredients in human papillomavirus vaccines," documents the presence in Gardasil/Gardasil 9 of a highly toxic chemical used in biological warfare with known side effects congruent with those reported from vaccination.[12] Governments in other counties have withdrawn the vaccine and many law suits are pending worldwide for failure to inform.
https://www.oatext.com/the-expanding-cocktail-of-harmful-ingredients-inhuman-papillomavirus-vaccines.php#gsc.tab=0

It seems dentists want in on the Gardasil cash cow before the cow is widely known to be deadly. Our kids are the collateral damage from such profiteering . Please protect our children and oppose SB 808. (I have included charts,links and papers to support my testimony) Thank you.

Emily Tarsell

References:

Certain high risk HPV types are associated with (but not proven to be causally related to) vaginal, vulva, penile,throat and anal cancers. [2,3] According to the American Cancer Society and the CDC, all of these cancers are rare in the US ranging between 3.1 per 100,000 for throat cancer to 1 in 100,000 for penile cancer and they occur mainly in older adults between 58 and 70 years. [4,5,6,7,8,9]. Risk factors for all of these cancers include smoking, alcohol, HIV infection and a compromised immune system. . The HPV vaccines were licensed to allegedly prevent cervical cancer not other cancers and the vaccine has not actully been proven to prevent these cancers.[5,6,10]

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Allini M, Costa J., et al. HPV infection and p53 and p16 expression in esophageal cancer: are they prognostic factors? *Infectious Agents and Cancer*2017**12**:54 https://doi.org/10.1186/s13027-017-0163-4 13 October 2017 :

Background

Esophageal squamous cell carcinoma (ESCC) is a highly lethal malignant tumor. Currently, Human papillomavirus (HPV) is suggested as a potential risk factor for esophageal cancer (EC) in addition to the classic risk factors, alcohol and tobacco, but this hypothesis still remains contradictory. We sought to investigate wether HPV and well-known biomarkers (p16 and p53) and patient-related factors that may have impact on survival of ESCC.

Conclusion : HPV infection and p53 and p16 expression are not prognostic factors in ESCC.

Other key features of the ADRs reported with HPV vaccines are the diversity of the symptoms and their development in a multi-layered manner over an extended period of time. The ADRs include c consciousness; systemic pain, including headache, myalgia, arthralgia, back pain and other pain; motor dysfunction, such as paralysis, muscular weakness, exhaustion and involuntary movements including dizziness, hypotension, tachycardia, nausea, vomiting and diarrhoea; respiratory dysfunction, including dyspnoea and asthma; endocrine disorders, such as menstrual disorder a symptoms, such as anxiety, frustration, hallucinations and overeating; higher brain dysfunction and cognitive impairments, including memory impairment, disorientation and loss of concent In some cases, these symptoms impair learning and result in extreme fatigue and decreased motivation, having a negative impact on everyday life (**8**, **9**, **10**, **11**). The situation in Japan is similar to serious and complex symptoms that develop across multiple body systems over an extended period of time (**12**, **13**).

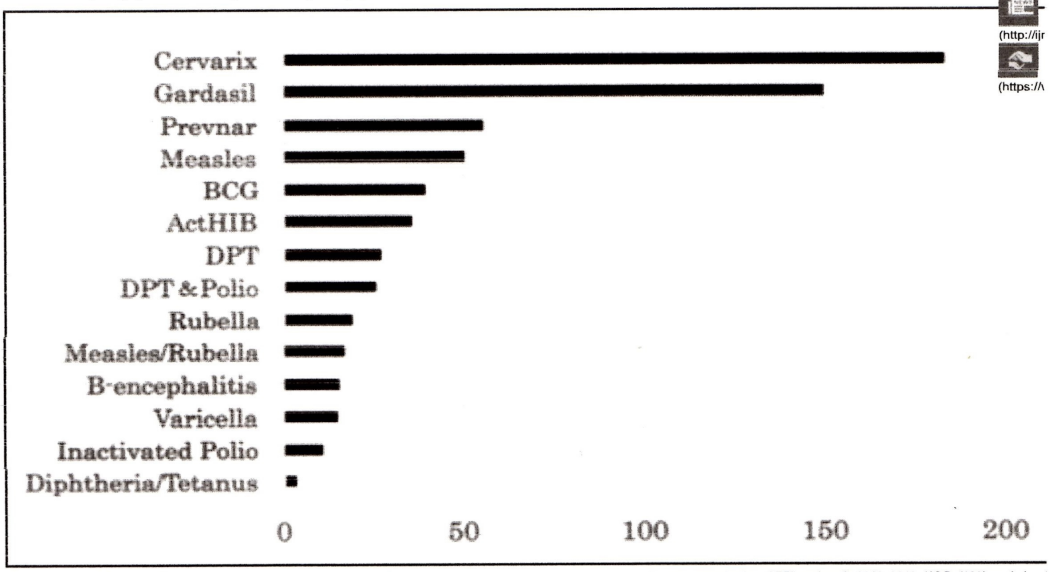

Fig. 1: Severe ADRs from HPV vaccines and other vaccines in Japan. Data sourced from the national adverse events following immunisation (AEFI) registry in 2013–2016. (ADRs/106inoculations, Bacillus Calmette–Guerin; DPT: diphtheria–pertussis–tetanus

Above chart compares Adverse Event Reports for the HPV vaccines (Cervarix and Gardasil) compared to all other childhood vaccines.

HPV-associated Cancers: Incidence

Rates are per 100,000 and are age-adjusted to the 2000 U.S. Standard Population
*** Incidence Rates based on case counts of 1-15 are suppressed per MDH/MCR Data Use Policy*
Incidence Source: SEERstat static data as of 01/03/2018.

Cancer	Incidence Count	Incidence Rate
Cervical	**228**	**6.7**
Anal	**140**	**2.0**
Penile	**13**	******
Vaginal	**31**	**0.8**
Vulvar	**95**	**2.6**
Oropharyngeal***	**185**	**2.4**

***Oropharyngeal cancer data reflect the incidence rates *for Tonsil and Oropharynx cancer.*
Note: Cancers have varying levels of association with HPV. Inclusion in this presentation does not imply that each case was associated with HPV infection

SB808 OPPOSE Written.pdf
Uploaded by: Williams, Peggy
Position: UNF

SB808 UNFAVORABLE Written testimony, 2/26/21

- My child's dentist does not replace our visits to the doctor, the discussions about medical and medical conditions we have in the doctor's office. I don't feel comfortable having a dentist recommending vaccines or giving one to my child. How much do dentists know about autoimmune disorders? If my child has an autoimmune condition would a dentist be aware that a vaccine could cause an adverse event? Would a dentist's two-hour training on vaccine adverse events cover this? Even with a doctor's prescription, and with the CDC-recommended vaccines being added to what a dentist can administer, this equals more vaccines being given with less exchange of information. How is this in the best interests of our children?

- This bill allows for children to be administered the COVID vaccine. COVID vaccines have not been tested on children.

- This bill does not stipulate the need for parental consent for minors.

- The agenda behind this bill is to increase the uptake of HPV vaccines and COVID "vaccines," with the potential that medical information is not sufficiently evaluated between all necessary parties. Neither one of these has been properly safety-tested. HPV vaccines were not tested against a true placebo, they have never been proven to prevent cancer even though it is being promoted as such. HPV infections clear on their own 95% of the time. The rate of occurrence for HPV-related cancer relative to other cancers is miniscule. If a person is infected with HPV at the time of vaccination, or if they have antibodies to one of the viruses in the vaccine, they are at much higher risk of developing cervical lesions, which can lead to cervical cancer. The age of occurrence for HPV-related cancers is 50 and older and minors can make their own decision to get this vaccine once they turn 18.

- This bill allows for potential multiple other CDC-approved vaccines to be given concurrently with the HPV vaccine, the effects of which have not been studied. This is dangerous.

- One cannot sue the vaccine manufacturer in the case of injury or death.

Thank you.

Peggy Williams

103 Wiltshire Ln

Severna Park, MD 21146

Oppose_SB808.pdf
Uploaded by: Yefimov, Olga
Position: UNF

Dear Senators,

I strongly urge you to OPPOSE bill SB808, which would allow dentists to vaccinate kids. Children should see a pediatrician for shots!

Children have a complicated immunization schedule that requires a trained professional (pediatrician) to assess appropriateness and readiness. The CDC recommended schedule is just a recommendation. Child's pediatrician needs to perform an assessment every time before vaccination.
https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html

The best health outcomes for children occur when the full doctor, parent, patient relationship is respected. None of these can be removed!

Thank you so much for your work!
Olga Yefimov,
Gaithersburg, MD

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March 2, 2021

To: The Honorable Paul G. Pinsky
Chair, Education, Health, and Environmental Affairs Committee

From: The Office of the Attorney General, Health Education and Advocacy Unit

Re: Senate Bill 808 (Health Occupations- Licensed Dentists- Administration of Vaccinations): Letter of Concern

The Office of the Attorney General's Health Education and Advocacy Unit (HEAU) has concerns about Senate Bill 808 which would authorize dentists to administer vaccinations in much the same way that pharmacists are authorized by § 12-508 of the Health Occupations Article. Dentists would be allowed to administer (1) flu vaccines to children aged 9-18, (2) childhood vaccinations on the Centers for Disease Control and Prevention's (CDC) Recommended Immunization Schedule to children 11-18 years old, if prescribed by an authorized prescriber, and (3) to adults, vaccines listed in the CDC's Recommended Immunization Schedule or the CDC's Health Information for International Travel.

The HEAU acknowledges there may be value in increasing the availability of vaccinations to adults, and that pharmacists are allowed to administer vaccinations to children. But dentists provide services in a way that pharmacists do not, increasing the risk of misapprehension by some parents that childhood immunizations delivered by a child's dentist are acceptable substitutes for pediatrician visits, when they are not. We believe dentists and pharmacists should be required to expressly recommend parents take their children to the pediatrician for office visits, in keeping with recognized guidelines.

The HEAU has long advocated for accessible, affordable health care for families in Maryland, many of whom now have improved access to pediatricians, primary care providers and preventive care services like vaccinations, often without out-of-pocket costs

under improved insurance coverage. We are concerned that vaccination services that are covered when delivered by pediatricians and primary care providers may not be covered in the same way by private insurance because dentists are not usually on medical insurance provider panels. This places patients who would likely have no-cost coverage of the services at risk for surprise bills.

Based on similar concerns, this committee adopted an amendment to Senate Bill 84 (Pharmacists – Administration of Self–Administered Medications and Maintenance Injectable Medications) requiring a pre-service Medical Billing Disclosure. We believe a disclosure tailored to the delivery of vaccines by dentists as proposed in this bill would mitigate our concerns. The document could also include the recommendations about pediatric care for minor patients.

Thank you for considering our concerns.

cc: Sponsor