

## **Policy and Advocacy Committee (May 2015 – December 2016)**

**May 4, 2015**---The Coalition for Abortion Access & Reproductive Equity (CAARE) of which AMWA is a member is continuing to work to remove abortion restriction riders in the Appropriations process. Almost 60 organizations signed on to the letters we distributed last year to draw attention to this effort, and we want to surpass that number this year. We hope that you will add your voice and demonstrate support for lifting restrictions on coverage of abortion care! We are circulating two letters this year:

1. Letter to Senators Cochran and Mikulski, Chair and Ranking Member of the Senate Committee on Appropriations, on all policy riders that restrict funding for abortion coverage.
2. Letter to Representatives Rogers and Lowey, Chair and Ranking Member of the House Committee on Appropriations, on all policy riders that restrict funding for abortion coverage.

AMWA filled-out the form to sign us-up for this action.

**May 14, 2015**---AMWA signed onto policies to help mitigate the rate of firearm injuries and deaths in the U.S. announced by the American College of Physicians, 7 other national health professional organizations, and the American Bar Association in a paper published in the Annals of Internal Medicine in February 2015. The organizations support a public health approach to reducing firearm injuries and fatalities, similar to approaches used to reduce tobacco use, motor vehicle fatalities, and unintentional poisoning. The paper recommends ways to reduce firearm-related injuries and death:

- Support criminal background checks for all firearm purchases, including sales by gun dealers, sales at gun shows, and private sales from one person to another;
- Oppose state and federal mandates that interfere with physician free speech and the patient-physician relationship, including physician "gag laws" that forbid physicians to discuss a patient's gun ownership;
- Oppose the sale or ownership of "assault weapons" and large-capacity magazines for private citizens; and
- Advocate for research into the causes and consequences of firearm violence and unintentional injuries so that evidence-based policies may be developed.

The American Bar Association notes in the paper that these recommendations "are constitutionally sound." The health professional societies made 2 additional recommendations:

- Support improved access to mental health care, with caution against broadly including all persons with any mental or substance use disorder in a category of persons prohibited from purchasing firearms; and -
- Oppose blanket reporting laws that require physicians to report patients who are displaying signs that they may cause serious harm to themselves or others, as these laws may stigmatize patients with mental or substance-abuse use disorders and inhibit them from seeking treatment.

ACP was joined by the American Academy of Family Physicians, the American Academy of Pediatrics, the American College of Emergency Physicians, the American Congress of Obstetricians and Gynecologists, the American College of Surgeons, the American Psychiatric Association, and the American Public Health Association, as well as the American Bar Association in its call to action.

**May 18, 2015**---As a member of the Patient, Consumer, and Public Health Coalition, AMWA is joining to write to express our strong concerns about the 21<sup>st</sup> Century Cures legislation. At the recent E&C Subcommittee on Health markup of the 21<sup>st</sup> Century Cures Act, Committee Ranking Member Frank Pallone stated that the Act was “far from a finished product,” and the Health Subcommittee Ranking Member Gene Green said there is “still work to do.” We agree. Several sections of the Act would lower standards for the approval of antibiotics, medical devices, and most prescription drugs – putting patients at unnecessary risk of injury or death. A few of our specific concerns are below.

If these provisions are fixed in Committee, we will be able to support the Bill. But as currently written, the FDA provisions of 21st Century Cures violates the basic tenet of medical care--"First, do no harm." The FDA provisions are more geared toward helping industry than helping patients. Patients deserve an FDA that keeps unsafe and ineffective pharmaceuticals and medical devices (including software) off the market by evaluating their risks and benefits as carefully as possible, in addition to as quickly as possible. These revisions are necessary to provide those safeguards for all patients. The bill further erodes FDA standards by allowing drug companies to submit short summaries about the safety and effectiveness of already approved drugs, instead of providing actual evidence to support what is stated in the summaries. This would apply to new indications, even when drugs were approved in expedited pathways

Even more egregious, the bill states that “nothing in this section prohibits the Secretary from using evidence from clinical experience for purposes not specified in based on preliminary, inconclusive data in this section,” which suggests clinical experience could possibly be used as evidence to support FDA approval for new medical products as well. Overall, the wording of these sections is so vague that it could eviscerate the FDA’s ability to make informed judgments about the safety or effectiveness of any drug, device, or vaccine.

This section would create a new pathway for approving antimicrobials that would discourage the use of large, well-designed, randomized, controlled clinical trials, which are the gold standard for assessing safety and effectiveness. Instead, the proposed pathway would force the FDA to enter into a written agreement early in the clinical development program that would allow approvals based on preliminary, uncontrolled clinical studies alone. The drugs would be tested on small numbers of patients (a limited population) but could then be prescribed for all patients without clear evidence that it is beneficial for all patients. That would be harmful to patients.

This section would create a new pathway for approving antimicrobials that would discourage the use of large, well-designed, randomized, controlled clinical trials, which are the gold standard for assessing safety and effectiveness. Instead, the proposed pathway would force the FDA to enter into a written agreement early in the clinical development program that would allow approvals based on preliminary, uncontrolled clinical studies alone. The drugs would be tested on small numbers of patients (a limited population) but could then be prescribed for all patients without clear evidence that it is beneficial for all patients. That would be harmful to patients.

It is important to note that while antibiotic resistance is a public health problem that is related to the lack of financial incentives to develop new antibiotics, the issues are different for antifungals. If Congress lowers the standards for antifungals as described in this provision that would be very harmful to patients without providing a benefit.

No peer-reviewed journals scrutinize the accuracy of the data submitted; they only review the interpretation of the data provided. In contrast, the FDA has access to the complete trial protocols and datasets, can inspect clinical trial sites to monitor trial conduct, and often re-analyzes data to determine its accuracy. Moreover, some peer-reviewed medical journals have a track record of publishing anything that is submitted. In addition to their questionable accuracy, peer reviewed studies would not necessarily include women, racial and ethnic minorities, people over 65, or children.

This section defines “health software” and exempts it from FDA regulation. The proposed definition of “health software” includes Electronic Health and Medical Records (EHRs and EMRs) (under Section 2241(1)(C)) and software which guides treatment decisions by physicians (under Section 2241(1)(F)). This puts patients at risk, because if this software is inaccurate, patients can be harmed just as they would by other types of medical devices.

The bill states that the FDA could regain the ability to regulate software which guides treatment decisions by physicians (Section 2241(1)(F)) under narrow circumstances. We disagree that health software should be exempt from FDA regulation. However, if it is exempted in this bill, the process for regaining regulatory authority needs to be clearly described and should not be burdensome to the agency. In addition, EHRs and EMRs (defined under Section 2241(1) (C)) should be added to the type of software FDA could regain the ability to regulate.

**June 2, 2015**---AMWA signed onto The Commission to End Health Care Disparities (the Commission) and the recommendations offered are based on the report, which was adopted by the Commission and published in 2011, entitled *Collecting and Using Race, Ethnicity and Language Data in Ambulatory Settings: A White Paper with Recommendations*.<sup>i</sup> We write to provide input into the Office of the National Coordinator for Health Information Technology Notice of Proposed Rulemaking for 2015 Health Information Technology Certification Criteria regarding race, ethnicity, preferred language, gender identity, sexual orientation, disability, and social and behavioral factors data collection. **HIT should support accurate demographic data collection, a facilitated display of performance data, and two-click access to displays of performance data stratified by any key demographic group.** We appreciate the opportunity to offer these suggestions and stand ready to assist in your important work.

**June 2, 2015**---AMWA as a member of the Patient, Consumer, and Public Health Coalition, which includes organizations representing patients, consumers, health professionals, and scientists, has admired Rep. Lois Capp’s work on behalf of improving the quality of public health. We, as part of the coalition read her May 14, 2015 statement

of support for the 21<sup>st</sup> Century Cures Act, stating that it would result in more children and seniors in clinical trials. However, the coalition's analysis of the bill finds that it suggests but does not require the changes needed to ensure their inclusion in clinical trials. And, unfortunately, there are several provisions in the bill that would have the opposite effect. Like you, Rep. Capps we are glad that there is language included in H.R. 6 (21<sup>st</sup> Century Cures Act, Section 1083) that calls for the National Institutes of Health Director to convene a workshop of experts on pediatric and geriatrics, provide guidelines, and make the findings of the workshop publicly available. However, the language does not mandate that more children and seniors will be included in clinical research, nor is there specific language anywhere in the bill that would do so. We encourage you to take a leadership role on this issue by including an amendment to the 21<sup>st</sup> Century Cures Act when it reaches the full House floor that would require that clinical trials include sufficient numbers of pediatric and patients over 65 in clinical research, including trials used as the basis of FDA approval decisions. The Coalition would welcome the opportunity to work with your staff on such an amendment

**June 2, 2015**---As long-time supporters of women's health and safety, The National Women's Network is once again writing to Congresspersons to thank them for their continuous support for the Food and Drug Administration's (FDA) stringent, evidence-based drug review process. You may be aware that a company seeking approval for a new drug to treat female sexual desire disorder is claiming that the FDA has displayed gender bias in its evaluation of the drug. We would like you to understand the perspective of the undersigned organizations, all of which have long and extensive experience advocating for women's health at the FDA. We are concerned about the safety and efficacy of this drug, flibanserin, and believe that women's health will be best served if the FDA is allowed to do its job of carefully weighing the evidence. As a Network we wrote to the FDA in March 2014 and again in May 2014 as we now do to support the FDA's concern for drug safety shown in what we believe is its appropriate handling of the flibanserin applications by rejecting its approval. We also appreciate your longstanding support for women's health and safety. *Even the Score's* effort to make this a conversation about gender equality is misleading and dangerous. The FDA should continue to balance a serious and respectful incorporation of patient input while maintaining a rigorous, science-based review standard for the drugs and devices it approves. We again agree with the disapproval of Flibanserin for the reasons FDA stated.

**June 9, 2015**---AMWA signed onto the AllTrials campaign to end the serious problem that only around half of all clinical trials ever conducted have reported results and thousands more have never even been registered. Information on what was done and what was found in these trials could be lost forever to doctors and researchers, leading to bad treatment decisions, missed opportunities for good medicine, and trials being needlessly repeated. The AllTrials campaign is calling for every **clinical trial, past and present, to be registered and their results reported**. Through the support of individual doctors and patients, professional societies and patient groups, we have already accomplished what many thought impossible. We changed the law in Europe so that clinical trials for drugs are now publicly registered and their results reported. We have even seen a

pharmaceutical company—GSK—sign our petition and join us at this year's annual meeting of the American Association for the Advancement of Science to explain why the time has come to share trial data present and past—and, more importantly, how it can be done.

**The AMWA statement:** AMWA joins the 85,000 people and 570 organizations that have publicly supported All Trials, a campaign practice that is transforming medical research and pharmaceutical practice. We agree that there is no need to waste research dollars and the effort of scientists by repeating work unnecessarily. We want every trial to have its work published and available regardless of whether the results are favorable or not.

**July 01 2015---** AMWA has signed on to a letter to President Obama regarding the United States restrictions on foreign aid that ban the ability to provide the full range of sexual & reproductive services, without discrimination. For more information go to: UPR of the US

**July 01 2015---** AMWA signs on to a coalition letter supporting the Pregnancy Workers Fairness Act promoted by the National Partnership for Women and Families thru because women should not lose their job or financial security because of a pregnancy. You can take action as well. Follow this link to read the letter and add your name: For more information on the bill, check out our website: <http://www.nationalpartnership.org/issues/fairness/pregnant-workers-fairness-act.html>.

**July 12 2015---** The American Medical Women's Association agrees that all clinical trials results should be reported and signs on to this letter with support. AllTrials has united patients and doctors, professional societies and patient groups to tackle the pressing problem of missing clinical trial data. You can endorse AllTrials campaign with an email to [alltrials@senseaboutscienceusa.org](mailto:alltrials@senseaboutscienceusa.org) ([ccingtrevor@senseaboutscienceusa.org](mailto:ccingtrevor@senseaboutscienceusa.org) and [jcockerill@senseaboutscience.org](mailto:jcockerill@senseaboutscience.org)).

**July 29, 2015--** AMWA will be signing on to the attached (draft) letter supporting Planned Parenthood health centers from being opposed from receiving federal public health funding. It was sent to the Hill 08/03/2015. Every day, we see the harmful impact that unequal access to health care has on women and communities across the country, and we therefore strongly support policies that improve access to affordable, quality health care. Policies that would deny Planned Parenthood public health funds only serve to cut millions off from critical preventive care, and we strongly oppose any effort to do so.

Should you have any questions, please contact ACOG Government Affairs staff, Rachel Gandell at 202-863-2534 or rgandell@acog.org.



American Medical Women's Association  
The Vision and Voice of Women in Medicine since 1915

The Honorable Mitch McConnell  
Senate Majority Leader  
S-230, U.S. Capitol Building  
Washington, DC 20510

The Honorable John Boehner  
Speaker of the House of Representatives  
H-232, U.S. Capitol Building  
Washington, DC 20515

October 7, 2015

Re: Support for Federal Funding for Planned Parenthood

Dear Leader McConnell and Speaker Boehner:

As an organization representing women health care professionals and the people they serve across the country, the American Medical Women's Association, AMWA, strongly opposes efforts to prevent Planned Parenthood health centers from participating in federal health programs, including Medicaid and the Title X family planning program.

Planned Parenthood provides a wide range of preventive health care services, including lifesaving screenings for breast and cervical cancer, birth control, well women exams, and testing, treatment, and counselling for HIV and other sexually transmitted diseases. Planned Parenthood professionals are highly trained doctors and nurses and other health care professionals who follow up to date standards and guidelines that ensure that the care provided is of the highest quality.

Defunding Planned Parenthood would prevent millions of women and men across the United States from getting basic preventive health care and contraception. In fact 2.7 million women rely on Planned Parenthood for health care and for many women Planned Parenthood is their only source of care. Planned Parenthood provides almost half a million screenings for cervical cancer and for breast cancer, 2 million contraceptive services, and nearly 4.5 million tests and treatment for sexually transmitted infections. For many women, Planned Parenthood is their sole source of health care. People come to Planned Parenthood because they know that they will be cared for compassionately and confidentially.

**American Medical Women's Association**  
12100 Sunset Hills Road • Suite 130, Reston, VA 20190 • Telephone (703) 234-4069 • Fax: (703) 435-4390 • [www.amwa-doc.org](http://www.amwa-doc.org)

**August 25, 2015 --** AMWA support letters from SB 128. End-of-Life Option Act (SB 128). This legislation would allow a mentally competent, terminally ill person in the final stages of their disease to request medication from a physician to bring about a peaceful death. The availability of this option can also provide peace of mind to those who are dying and for their families. The extensive, and important, safeguards in SB 128 will ensure that the choice made by a terminally ill person to access aid in dying is informed, deliberate and voluntary.

<https://www.compassionandchoices.org/what-you-can-do/get-involved/support-of-the-end-of-life-option-act-sb-128/>

**September 03, 2015 –** AMWA supports sign-on letter that will be sent to Hill prior to the hearing. The Senate Judiciary Committee is planning to hold a hearing on the 20-week abortion ban legislation introduced by Sen. Lindsey Graham in mid-to-late September.

<http://prh.org>

**October 09, 2015--** The American Medical Women's Association (AMWA) agrees that the boxed warning on the package label for low-dose vaginal estrogen discourages clinicians from prescribing the product and women from taking it even after purchase. The current boxed warning, states "WARNING: ENDOMETRIAL CANCER, CARDIOVASCULAR DISORDERS, BREAST CANCER, and PROBABLE DEMENTIA. This wording is not appropriate for low dose estrogen products used to treat vulvovaginal atrophy (VVA). This condition, also known as genitourinary syndrome of menopause, is a common and progressive condition that adversely affects the health and quality of life of many postmenopausal women . To improve the quality of life and provide appropriate treatment and education, we join the NAMS, and other organizations in requesting that the labeling for low dose estrogen products be changed and the current warning be dropped. <http://www.menopause.org/forms/nams-citizens'-petition>

September 16, 2015

Dear Member of the Senate,

We, the undersigned medical and public health organizations, stand in strong opposition to S. 1553<sup>1</sup>, the so-called “Pain-Capable Unborn Child Protection Act,” sponsored by Senator Lindsay Graham (R-SC). Politicians should not interfere in personal, medical decisions.

If enacted, S. 1553 would ban most abortions in the United States at 20 weeks after fertilization, clearly before viability. The bill threatens providers with criminal fines and/or imprisonment and civil actions for providing professional and compassionate care, and is intended to intimidate and discourage doctors from providing abortion care. This bill places health care providers in an untenable situation – when they are facing a complex, urgent medical situation, they must think about an unjust law instead of about how to protect the health and safety of their patients.

S. 1553 ignores the health issues and real life situations that women can face in pregnancy. Every woman faces her own unique circumstances, challenges, and potential complications. She needs to be able to make decisions based on her physician’s medical advice and what is right for her and her family.

S. 1553 is identical to H.R. 36 passed by the House of Representatives in May. Before moving to the floor, H.R. 36 was amended under the guise of improving the bill. But the bill continues to illustrate a disregard for standards of medical care and women’s health. The changes did nothing to temper the bill’s extremity, and instead further injected ideological agendas between women and their doctors. S. 1553 contains a requirement that adult survivors of rape receive counseling or medical treatment for the rape at least 48 hours prior to their abortion procedure. For minors, the bill would require reporting to law enforcement of rape or incest. This language does not improve the bill in any way, but instead mandates delays in needed medical care. Women’s health care providers are appropriately trained and able to provide quality counseling to women, no matter what circumstances she is facing in her life. Requiring a woman to attend extra appointments and face further barriers to care before she is able to access care she needs is against the tenets of medical practice.

Further, the bill includes medically inappropriate and unnecessary requirements dictating how providers should deliver medical care.<sup>2</sup> Reproductive health care providers, based on their extensive training and informed by professional practice guidelines, should be determining with their patients the best course of action. The bill also contains a provision requiring physicians to report any abortion performed after twenty weeks and the location of the abortion. While the bill specifically includes protections to ensure that such reporting does not reveal the identity of a woman

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<sup>1</sup> S. 1553 is the Senate counterpart to H.R. 36, which the House of Representatives passed on May 13, 2015.

<sup>2</sup> A recently published New England Journal of Medicine study on neo-natal care and fetal survival has been incorrectly cited as questioning the science around viability. The article evaluated differences in hospital practices for extremely premature births and is not related to the issue of second trimester abortions. Rysavy, Matthew A. et al. Between-Hospital Variation in Treatment Outcomes in Extremely Premature Infants. New England Journal of Medicine 372:19 (May 7, 2015).

**September 14, 2015** – AMWA supports willingness to join a medical coalition amicus brief in this case in the NM Supreme Court; empowering terminally ill patients with autonomy over end of life decision-making, and in particular aid in dying. AMWA will supply a notice of intention to file a brief on 9/16 and a final brief on 9/30.

[www.disabilityrightslegalcenter.org](http://www.disabilityrightslegalcenter.org)



**September 29,2015—AMWA supports**

**October 01,2015**—AMWA Signs on letter for Senate regarding women in clinical trials  
(See below):

September x, 2015

Senator Lamar Alexander  
Chairman  
United States Senate  
Committee on Health, Education, Labor & Pensions  
428 Dirksen Office Building  
Washington, D.C. 20510

Senator Patty Murray  
Ranking Member  
United States Senate  
Committee on Health, Education, Labor & Pensions  
428 Dirksen Office Building  
Washington, D.C. 20510

Dear Chairman Alexander and Senator Murray,

The undersigned organizations strongly support the Senate Committee on Health, Education, Labor, and Pensions (HELP) Committee's efforts to improve patients' access to safe and effective medical products in a timely manner through the Innovations for Healthier Americans Initiative.

One critical area that needs to be examined is healthcare disparities that exist between men and women due to the way medical research is conducted in the United States. We urge the Committee to consider the inclusion of components of the Research for All Act of 2015 within the legislative text of the Innovations initiative.

The Research for All Act codifies the new NIH policies aimed at examining sex differences in basic research at the NIH. Biomedical research has historically utilized male research subjects disproportionately, creating a significant gap in knowledge regarding the extent to which disease processes and underlying physiology are influenced by biological sex. The lack of inclusion of females in pre-clinical basic research has resulted in treatments that sometimes are less effective or less safe in women. The NIH has recognized this gap and announced policies to balance the study of males and females in preclinical research. With this announcement, the NIH has begun to take steps towards achieving equity in biomedical research, yet significant questions remain on how well this will be implemented throughout the Agency. Therefore, codification through legislation is necessary and will demonstrate Congressional support for this critical change.

The Research for All Acts provisions regarding the FDA would have an even more immediate and important impact. The Research for All Act directs the FDA to ensure that the design and size of clinical trials for products granted expedited approval under any program within section 506 of the Federal Food, Drug and Cosmetic Act, are

sufficient to determine the safety and effectiveness of such products for both men and women. The Agency has signaled it is currently moving in that direction for studies in general, but the voluntary, unenforced efforts have had a limited impact thus far. Including this in the law is necessary to ensure that important new medications are tested to determine if they are safe and effective for women and men. Although the Research for All Act includes that provision only for expedited drugs, ideally, that provision would apply to all clinical trials submitted in support of new drug and device approvals.

Additionally, the Research for All Act provides for increased communication with the Agency and rolling review of applications for new drugs and biologics to ensure that new drugs will be safe and effective for both men and women.

Further, the Research for All Act includes provisions to update Government Accountability Office (GAO) reports on women and minority inclusion in medical research at the NIH and FDA. The GAO is due to release a report on inclusion at the NIH in the coming month; however, reports on these topics at the FDA have not been updated in over a decade and this information is imperative to ensuring our federal health and research agencies are including representative groups in medical research that guide treatment decisions.

Thank you for your leadership in support medical and health services research and its commitment to the health of the nation. We look forward to continuing to work with you to build a healthier future for all Americans.

Sincerely,

Center for Science and Democracy at the Union of Concerned Scientists  
Jacobs Institute for Women's Health  
National Center for Health Research  
National Consumers League  
National Women's Health Network  
The Society for Women's Health Research  
WomenHeart

cc:

Senator Michael B. Enzi  
Senator Richard Burr  
Senator Johnny Isakson  
Senator Rand Paul  
Senator Susan Collins  
Senator Lisa Murkowski  
Senator Mark Kirk  
Senator Tim Scott  
Senator Orrin Hatch  
Senator Pat Roberts  
Senator Bill Cassidy, M.D.

Senator Barbara Mikulski  
Senator Bernie Sanders  
Senator Robert P. Casey, Jr  
Senator Al Franken  
Senator Michael F. Bennet  
Senator Sheldon Whitehouse  
Senator Tammy Baldwin  
Senator Christopher S. Murphy

**October 04, 2015--** The American Medical Women's Association would like to help increase prevention efforts to young people through outreach with parent, school, and

local organizations to promote safe medication use practices among families through education about safe drug use and dangers of overdose or interactions with other medications or substances; education about safe drug storage and disposal practices. AMWA will use readily available materials through [fda.gov](http://fda.gov) and other reputable agencies.

**October 27, 2015--** The American Medical Women's Association signs on to HEAL's TVPA Anniversary Letter (see attached) to President Obama, urging the White House Office of Management and Budget (OMB) to request increased funds in the President's FY17 budget to combat human trafficking and forced labor.

October 2015 marks the 15th anniversary of the enactment of the federal Trafficking Victims Protection Act (TVPA). This landmark legislation, reauthorized four times, laid the foundation for significant efforts in the United States to combat human trafficking and support trafficking survivors. At this important juncture, we celebrate the TVPA while acknowledging that the prevention of human trafficking and the promotion of well-being among survivors requires improved, dedicated resources for health and social services.

Human trafficking is a healthcare issue, with severe and long-lasting adverse consequences for the health, development, and well-being of victims and survivors. Current U.S. Government funding is insufficient to meet the health, housing, and rehabilitative care needs of victims and survivors. The collective voice of the health sector must urge for greater U.S. investment in programs that prevent human trafficking, and provide comprehensive health services to victims of violence.

Please sign on to HEAL's TVPA Anniversary Letter (see attached) to President Obama, urging the White House Office of Management and Budget (OMB) to request increased funds in the President's FY17 budget to combat human trafficking and forced labor. To endorse as an individual, please [click here](#) or as an organization, [click here](#), by October 26th, 5pm EDT.

In solidarity,  
Susie Baldwin, MD, MPH  
Hanni Stoklosa, MD, MPH

Directors, HEAL Trafficking



Health, Education, Advocacy, Linkage  
*Because Human Trafficking is a Health Issue*  
HEALTrafficking.org

Dear President Obama,

In honor of the 15<sup>th</sup> anniversary of the Trafficking Victims Protection Act (TVPA), HEAL (Health, Education, Advocacy, Linkage) Trafficking and the undersigned individuals and organizations call for an improved health sector response to prevent human trafficking and promote care for trafficked persons. We urge that the President's FY 2017 Budget proposal include increased resources to support the essential efforts and initiatives described in this letter.

HEAL Trafficking unifies and mobilizes interdisciplinary professionals combating human trafficking through a healthcare lens and serves as a centralized resource on health for the broader anti-trafficking community. Our members include leaders from clinical practice, public health, law, global health, academia, and government, working at national and international levels. In addition to HEAL members, the undersigned include a broad array of organizations and individuals playing key roles in the health sector's response to human trafficking.

This request is consistent with the "4P" paradigm: Prevention, Protection, Prosecution, and Partnerships of the U.S. Department of State's Office to Monitor and Combat Trafficking in Persons, and with the Federal Strategic Action Plan on Services for Victims of Human Trafficking in the United States (2013-2017).

HEAL Trafficking and the undersigned individuals and organizations celebrate the 15 years of the Trafficking Victims Protection Act (TVPA) and its reauthorizations. Towards the advancement of the TVPA and the full achievement of its goals, we offer these suggestions for improving and expanding the health sector's response to human trafficking in the United States:

1. Medical Education: We strongly support training and educating health care providers to recognize trafficked persons and respond effectively to potential cases. Such training should be grounded in a patient-centered, culturally relevant, evidence-based, gender-responsive, trauma-informed perspective for identifying and treating victims of intentional violence, in general, and should build upon existing educational modalities such as those that educate providers about intimate partner violence. Trauma-informed care should be integrated into health professional training across specialties, clinical practice and professional titles. This training would improve care for survivors of intentional violence, including trafficking, by advancing treatment approaches, preventing re-traumatization and harm, enhancing identification of survivors, and disrupting survivors' cycle of violence and trafficking.<sup>1</sup>
2. Credentialing for Trauma-Informed Care: We support facility-based accreditation for provision of trauma-informed care.<sup>2</sup> Implementation of this suggestion could occur in collaboration with

<sup>1</sup> <http://www.ncbi.nlm.nih.gov/books/NBK207192/>

<sup>2</sup> <http://www.ncbi.nlm.nih.gov/books/NBK207194/>

**October 29, 2015--**The American Medical Women's Association signs on regarding the labeling of medical devices:



October 30, 2015

Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Maryland 20852

Comments of members of the Patient, Consumer, and Public Health Coalition  
on Medical Device Patient Labeling  
[Docket No. FDA-2000-D-0067]

As members of the Patient, Consumer, and Public Health Coalition, we appreciate the opportunity to comment on Medical Device Patient Labeling. The 2001 FDA Guidance on Medical Device Patient Labeling states that "medical device patient labeling is any information associated with a device targeted to the patient or caregiver. Medical device patient labeling can be in numerous formats, including patient brochures, user manuals, informational webpages, and online training videos. Patient labels should provide information such as proper use, risks and benefits, maintenance, and mode of action in language the patient or caregiver can read and

understand. We are commenting on current medical device patient labeling and on advancing development of labels.

### Comments on Current Medical Device Patient Labeling

We support the emphasis in the workshop on using human factors engineering to ensure they are understandable to the public. We strongly support FDA's objective evidence of usability. This requires labels to be written at an appropriate reading level as measured by a validated testing method and that labels be focus-group tested with a representative sample of potential users with a wide range of reading levels as well as health literacy levels. Although making the information understandable is key, it is equally important to make it as interesting to read and visually appealing as possible. Microscopic fonts and lack of white space has been a problem with labels for years, and that is a major reason why they are not read.

### Comments on Advancing Development

At the Medical Device Patient Labeling workshop, a couple of participants received less attention than they should have. As the 2001 Guidance states, there are two general categories of labels: (1) Risk-benefit information and (2) Instructions for use. While readability and organization of both types of labels are critical to assure safe and effective use, there are some considerations that differ for the two categories. For example, being concise was brought up many times as critical to the effectiveness of instructions for use. While avoiding wordiness and repetition is important and being concise is a desirable goal, **understandable and complete information are much more important for risk-benefit labels**, which are often key sources of information for patients while making healthcare decisions. Complete information does not, however, require the inclusion of information of no interest to patients. Patient booklets that are 20 or 30 pages long are almost never appropriate and putting risk information, contraindications, or warnings on page 8 or later is never appropriate. The most important information – risks and benefits – should be first.

Also, while labels are required to describe the *known* risks and benefits, labels should also clearly include what is *not known*. This is particularly important in the case where no clinical trials were conducted, no comparison samples were included in clinical trials, or surrogate endpoints rather than clinical outcomes were used to clear or approve the device. In these cases, the label should clearly state that the benefits or risks are patients' health are unknown at this time, or the benefits and risks compared to other treatment options are unknown.

In addition, labels should tell patients if the device is proven to be safe and effective for specific demographic subgroups, such as women, men, people of specific racial/ethnic groups, people who are over 65, or people with particular comorbid conditions. For most of the 20<sup>th</sup> Century, clinical trials were predominantly conducted on white men and the data was simply assumed to apply to all patients. However, increasingly research has shown that not to be true. For that reason, it is important for FDA to provide information about data analyses specific to those demographic subgroups on the device label. If no such subgroup analysis has been done, this should be stated explicitly on the label along with the reason why (for example, that there were not enough patients of that demographic in the clinical trial for an analysis to be performed).

Unfortunately, so little subgroup scientific data are available for most devices that it will be easy to provide this information in a sentence or two.

### **Conclusions**

Members of the Patient, Consumer, and Public Health Coalition strongly support the FDA's use of objective usability evidence and requiring labels to be written at an appropriate reading level that is easy and interesting to read. However, FDA should focus more on key issues around "advancing development" of labels such as noting on the label if risks and benefits were determined with surrogate endpoints, whether clinical trials were conducted, and whether the device was analyzed on subpopulations.

American Medical Student Association  
American Medical Women's Association (AMWA)  
Association for Pelvic Organ Prolapse Support  
Breast Cancer Action  
Connecticut Center for Patient Safety  
Jacobs Institute of Women's Health  
MISSD  
MRSA Survivors Network  
National Center for Health Research  
National Consumers League  
National Organization for Women (NOW)  
National Physicians Alliance  
Center for Science and Democracy at the Union of Concerned Scientists  
WoodyMatters

*The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or at [pb@center4research.org](mailto:pb@center4research.org)*

**December 11, 2015** - - AMWA signs on letter calling on Congress to end the ban on federal gun violence research, led by Democratic Leader Nancy Pelosi. Politico just published a story stating that Speaker Paul Ryan called Democratic Leader Nancy Pelosi personally to talk about the ban.

Dear Congress,

As medical and public health organizations representing health professionals across the country, we urge you to end the federal ban on gun violence research and fund this critical work. Gun violence is a grave public health epidemic resulting in the senseless deaths of 90 Americans every day.

As health care providers and public health professionals, we are overwhelmed in our emergency departments, clinics, offices, and communities with the victims of mass shootings, homicides, suicides, accidental shootings, and injuries every day. As we work to address the devastating and long- lasting emotional effects of gun violence on victims and their families, we are hampered by the lack of evidence- based research to use to point our communities towards proven programs that target gun violence prevention.

The effective ban on federal research has stymied our progress on gun violence prevention for the past 20 years. Former Representative Jay Dickey (R-AK), author of the current language that bans gun violence research, recently noted that, “it is my position that somehow or someday we should slowly but methodically fund [gun] research until a solution is reached. Doing nothing is no longer an acceptable solution.”

Over 2,000 physicians, 110 members of Congress, President Obama, Rep. Dickey and now the undersigned organizations are calling on you to allow research to resume. Americans deserve to feel safe knowing that we are working with the best tools and information in the fight to reduce gun violence.

**December 30, 2015--** AMWA signs on letter urging the FDA to strengthen their proposed rule and concludes by stating that since the harm of these products is primarily from the nicotine and other substances in the vapor, and not from the device itself, these products should be regulated as drugs rather than devices or combination products.

December 30, 2015

Division of Dockets Management (HFA-305)

U.S. Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

Comments of members of the Patient, Consumer, and Public Health Coalition  
on the proposed rulemaking

Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices,  
or Combination Products; Amendments to Regulations Regarding “Intended Uses”

[Docket No. FDA-2015-N-2002]

Regarding the above proposed rule, we are writing as members of the Patient, Consumer, and Public Health Coalition to recommend that the FDA broaden the rule’s focus to be more



consistent with the public health intent of the law, which is necessary because of numerous changes in tobacco products that have been introduced since the law passed.

In the final rule regarding jurisdictional boundaries between the Center for Drug Evaluation and Research (CDER) and the Center for Tobacco Products (CTP), FDA should list the principles that it will apply to the regulation of products containing nicotine, regardless of which Center has jurisdiction. The FDA should regulate all nicotine-containing products with the goal of minimizing the risks of all of these products, such as e-cigarettes, and ensure that all Americans fully understand those risks.

In its proposed rule, FDA notes that nothing in *Brown & Williamson* or *Sottera* limits its authority or jurisdiction over products made or derived from tobacco as drugs or devices, if they fall under the disease prong definition. If a product claims to reduce nicotine withdrawal symptoms (cravings associated with quitting smoking) or prevents relapses, then the product is intended to cure or treat nicotine addiction. This brings it within the definition of a drug and under the FDA's drug and device jurisdiction.

We agree with the FDA that "consumers are particularly susceptible to confusion where products made or derived from tobacco. . .make claims related to quitting smoking." [i] Such claims should be scrutinized by the FDA to prevent consumers from becoming confused or misled. Disclaimers are insufficient because some manufacturers of e-cigarettes have made claims that do not meet the requirements for the marketing of drugs and devices. Scrutinizing these and other explicit or implicit claims for products now on the market should be an FDA priority.

In the Federal Register notice, the FDA concludes that it retains the ability to regulate tobacco products, if the claims relate to the effects of nicotine that were not commonly and legally made in the marketing of cigarettes and smokeless tobacco products prior to the date of the Supreme Court's decision in *Brown & Williamson*. FDA states that tobacco products in this category would include those marketed to "maintain healthy lung function," "relieve tension," "support the immune system," or "promote weight loss."<sup>1</sup> We strongly agree.

FDA cites a number of claims that would not lead a product to be categorized as a drug/device under the law. We agree that "claims related to satisfaction, pleasure and enjoyment," would not cause the product to be categorized as a drug/device, nor would the promotion of products with lifestyle claims.<sup>1</sup> The same is true for FDA's categorization of claims such as "smoke-free" or "full taste and satisfaction" or "spit free tobacco pleasure." However, FDA concludes that the claims "satisfying tobacco alternative" or that a tobacco product will provide the same effects as another tobacco product are tobacco claims;<sup>1</sup> however, these claims each imply that the product provides an alternative to the nicotine in cigarettes. The implicit claim is that these products address a tobacco user's nicotine craving, just as do products FDA concludes fall into the drug/device category. These types of claims should therefore not be permitted.

Today's marketplace for nicotine products is much different from the one that existed when nicotine was available only in traditional tobacco products or through FDA-approved cessation products. Older FDA policies may no longer be adequate. Under the *Sottera* decision, e-cigarettes are to be treated as tobacco products unless their manufacturers make therapeutic claims. But FDA's delay in adopting a final deeming rule has meant that e-cigarettes have been

marketed with no regulation at all. As a result, e-cigarettes have become freely available, and are widely marketed, and will continue to be marketed even after the deeming rule is in effect. The FDA therefore needs to immediately implement regulatory policies that reflect today's market.

In establishing jurisdictional lines between CDER and CTP, FDA should focus not only on the legal definitions of different products, but also on what division of responsibility best promotes the purposes of the regulation. The most effective regulatory policies should create incentives for manufacturers and sellers to develop products that can reduce addiction to and the risks of tobacco and nicotine products, encourage full cessation, and minimize use of any tobacco products by young people.

Current policies do not accomplish this goal. If products like e-cigarettes have a public health value, it would be to substantially increase the number of cigarette smokers who quit using tobacco completely or that deliver nicotine in the safest ways. However, manufacturers who wish to design products that are more likely to help smokers achieve either goal, and who want to promote them accurately and consistently with the evidence reviewed by FDA, face regulatory hurdles. In contrast, manufacturers who design and promote products as lifestyle choices, face few regulatory constraints. E-cigarettes should not be allowed to be promoted to initiate tobacco use, deter smokers from quitting, or encourage former smokers to reinitiate use. The FDA should ensure that consumers are aware of the risks of nicotine. Research should be required to determine how these products are used, by whom, and the exact risks and benefits before any health claims are permitted.

FDA should crack down on claims for products that have not been shown to be effective at helping smokers quit. FDA should focus on reducing the sale and marketing of nicotine-based products that appeal to youth and expand the market place for nicotine addiction. In order to avoid confusion in the marketplace, the same products should not be allowed to be marketed for cessation and for recreational purposes.

A comprehensive regulatory policy should include all the restrictions on marketing of all tobacco products subject to FDA jurisdiction that are included in the FDA's 2010 regulations on cigarettes. In addition, the sale of nicotine-based products to minors on the internet has created a major public health problem. FDA regulations should be designed to minimize youth usage, such as prohibiting certain flavored e-cigarettes.

Regarding newly deemed products (such as e-cigarettes), FDA must establish strict requirements that the manufacturer demonstrate that it is free of dangerous toxins and can be manufactured consistently to FDA specifications.

In conclusion, we urge the FDA to go beyond the proposed rule and strengthen it to include the appropriate regulation of products made or derived from tobacco as drugs, devices, or combination products under the FD&CA. However, since the harm of these products is primarily from the nicotine and other substances in the vapor, and not from the device itself, these products should be regulated as drugs rather than devices or combination products.

National Center for Health Research

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[i] Food and Drug Administration (September 25, 2015). Proposed Rule: Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ``Intended Uses."  
<http://www.regulations.gov/#!documentDetail;D=FDA-2015-N-2002-0001>

**January 5, 2016**—AMWA signs on letter regarding proposed FDA regulation of e-cigarettes and all nicotine-containing products; to recommend that the FDA broaden the rule's focus to be more consistent with the public health intent of the law, which is necessary because of numerous changes in tobacco products that have been introduced since the law passed. Sign on urges the FDA to go beyond the proposed rule and strengthen it to include the appropriate regulation of products made or derived from tobacco as drugs, devices, or combination products under the FD&CA. However, since the harm of these products is primarily from the nicotine and other substances in the vapor, and not from the device itself, these products should be regulated as drugs rather than devices or combination products.



December 30, 2015

Division of Dockets Management (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Comments of members of the Patient, Consumer, and Public Health Coalition  
on the proposed rulemaking  
*Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs,  
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American Medical Women's Association  
Connecticut Center for Patient Safety  
MedShadow Foundation  
MRSA Survivors Network  
National Center for Health Research  
U.S. PIRG  
Washington Advocates for Patient Safety  
WoodyMatters

*The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or at [pb@center4research.org](mailto:pb@center4research.org)*

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<sup>1</sup> Food and Drug Administration (September 25, 2015). Proposed Rule: Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding "Intended Uses." <http://www.regulations.gov/#/documentDetail;D=FDA-2015-N-2002-0001>

**January 05, 2016—**

The American Medical Women's Association (AMWA) is a staunch advocate for better gun safety measures in the United States to reduce fire arm related injuries.

AMWA Supports...

- A physician's right to discuss gun safety within the confines of the confidential patient-doctor relationship.
- Lifting the ban on federal funding for research related to gun violence as a public health problem.
- Adoption of education programs promoting firearm safety and responsible gun storage practices.
- Legislation and policy change that holds gun owners responsible for injury or death that occurs as a result of negligent gun storage practices.
- A ban on assault-type rifles and high-capacity magazines.
- Barring specific groups of people from purchasing firearms and ammunition.
- The expansion of mental health services, especially to children and young adults, and better treatments for patients suffering from alcohol and drug addictions.

THE WHITE HOUSE  
Office of the Press Secretary

#### FACT SHEET: New Executive Actions to Reduce Gun Violence and Make Our Communities Safer

Gun violence has taken a heartbreaking toll on too many communities across the country. Over the past decade in America, more than 100,000 people have been killed as a result of gun violence—and millions more have been the victim of assaults, robberies, and other crimes involving a gun. Many of these crimes were committed by people who never should have been able to purchase a gun in the first place. Over the same period, hundreds of thousands of other people in our communities committed suicide with a gun and nearly half a million people suffered other gun injuries. Hundreds of law enforcement officers have been shot to death protecting their communities. And too many children are killed or injured by firearms every year, often by accident. The vast majority of Americans—including the vast majority of gun owners—believe we must take sensible steps to address these horrible tragedies.

The President and Vice President are committed to using every tool at the Administration's disposal to reduce gun violence. Some of the gaps in our country's gun laws can only be fixed through legislation, which is why the President continues to call on Congress to pass the kind of commonsense gun safety reforms supported by a majority of the American people. And while Congress has repeatedly failed to take action and pass laws that would expand background checks and reduce gun violence, today, building on the significant



steps that have already been taken over the past several years, the Administration is announcing a series of commonsense executive actions designed to:

1. Keep guns out of the wrong hands through background checks.

- The Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) is making clear that it doesn't matter where you conduct your business—from a store, at gun shows, or over the Internet: If you're in the business of selling firearms, you must get a license and conduct background checks.
- ATF is finalizing a rule to require background checks for people trying to buy some of the most dangerous weapons and other items through a trust, corporation, or other legal entity.
- Attorney General Loretta E. Lynch has sent a letter to States highlighting the importance of receiving complete criminal history records and criminal dispositions, information on persons disqualified because of a mental illness, and qualifying crimes of domestic violence.
- The Federal Bureau of Investigation (FBI) is overhauling the background check system to make it more effective and efficient. The envisioned improvements include processing background checks 24 hours a day, 7 days a week, and improving notification of local authorities when certain prohibited persons unlawfully attempt to buy a gun. The FBI will hire more than 230 additional examiners and other staff to help process these background checks.

2. Make our communities safer from gun violence.

- The Attorney General convened a call with U.S. Attorneys around the country to direct federal prosecutors to continue to focus on smart and effective enforcement of our gun laws.
- The President's FY2017 budget will include funding for 200 new ATF agents and investigators to help enforce our gun laws.
- ATF has established an Internet Investigation Center to track illegal online firearms trafficking and is dedicating \$4 million and additional personnel to enhance the National Integrated Ballistics Information Network.
- ATF is finalizing a rule to ensure that dealers who ship firearms notify law enforcement if their guns are lost or stolen in transit.
- The Attorney General issued a memo encouraging every U.S. Attorney's Office to renew domestic violence outreach efforts.

3. Increase mental health treatment and reporting to the background check

system.

- The Administration is proposing a new \$500 million investment to increase access to mental health care.

- The Social Security Administration has indicated that it will begin the rulemaking process to include information in the background check system about beneficiaries who are prohibited from possessing a firearm for mental health reasons.

- The Department of Health and Human Services is finalizing a rule to remove unnecessary legal barriers preventing States from reporting relevant information about people prohibited from possessing a gun for specific mental health reasons.

#### 4. Shape the future of gun safety technology.

- The President has directed the Departments of Defense, Justice, and Homeland Security to conduct or sponsor research into gun safety technology.

- The President has also directed the departments to review the availability of smart gun technology on a regular basis, and to explore potential ways to further its use and development to more broadly improve gun safety.

Congress should support the President's request for resources for 200 new ATF agents and investigators to help enforce our gun laws, as well as a new \$500 million investment to address mental health issues.

Because we all must do our part to keep our communities safe, the Administration is also calling on States and local governments to do all they can to keep guns out of the wrong hands and reduce gun violence. It is also calling on private-sector leaders to follow the lead of other businesses that have taken voluntary steps to make it harder for dangerous individuals to get their hands on a gun. In the coming weeks, the Administration will engage with manufacturers, retailers, and other private-sector leaders to explore what more they can do.

### New Actions by the Federal Government

#### Keeping Guns Out of the Wrong Hands Through Background Checks

The most important thing we can do to prevent gun violence is to make sure those who would commit violent acts cannot get a firearm in the first place. The National Instant Criminal Background Check System (NICS), which was created by Congress to prevent guns from being sold to prohibited individuals, is a critical tool in achieving that goal. According to the Bureau of Justice Statistics, the background check system has prevented more than 2 million guns from getting

into the wrong hands. We know that making the system more efficient, and ensuring that it has all appropriate records about prohibited purchasers, will help enhance public safety. Today, the Administration is announcing the following executive actions to ensure that all gun dealers are licensed and run background checks, and to strengthen the background check system itself:

- Clarify that it doesn't matter where you conduct your business—from a store, at gun shows, or over the Internet: If you're in the business of selling firearms, you must get a license and conduct background checks. Background checks have been shown to keep guns out of the wrong hands, but too many gun sales—particularly online and at gun shows—occur without basic background checks. Today, the Administration took action to ensure that anyone who is “engaged in the business” of selling firearms is licensed and conducts background checks on their customers. Consistent with court rulings on this issue, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) has clarified the following principles:

- o A person can be engaged in the business of dealing in firearms regardless of the location in which firearm transactions are conducted. For example, a person can be engaged in the business of dealing in firearms even if the person only conducts firearm transactions at gun shows or through the Internet. Those engaged in the business of dealing in firearms who utilize the Internet or other technologies must obtain a license, just as a dealer whose business is run out of a traditional brick-and-mortar store.

- o Quantity and frequency of sales are relevant indicators. There is no specific threshold number of firearms purchased or sold that triggers the licensure requirement. But it is important to note that even a few transactions, when combined with other evidence, can be sufficient to establish that a person is “engaged in the business.” For example, courts have upheld convictions for dealing without a license when as few as two firearms were sold or when only one or two transactions took place, when other factors also were present.

- o There are criminal penalties for failing to comply with these requirements. A person who willfully engages in the business of dealing in firearms without the required license is subject to criminal prosecution and can be sentenced up to five years in prison and fined up to \$250,000. Dealers are also subject to penalties for failing to conduct background checks before completing a sale.

- Require background checks for people trying to buy some of the most dangerous weapons and other items through a trust or corporation. The National Firearms Act imposes restrictions on sales of some of the most dangerous weapons, such as machine guns and sawed-off shotguns. But because of outdated regulations, individuals have been able to avoid the background check requirement by applying to acquire these firearms and other items through trusts, corporations, and other legal entities. In fact, the number of these applications has

increased significantly over the years—from fewer than 900 applications in the year 2000 to more than 90,000 applications in 2014. ATF is finalizing a rule that makes clear that people will no longer be able to avoid background checks by buying NFA guns and other items through a trust or corporation.

- Ensure States are providing records to the background check system, and work cooperatively with jurisdictions to improve reporting. Congress has prohibited specific categories of people from buying guns—from convicted felons to users of illegal drugs to individuals convicted of misdemeanor crimes of domestic violence. In the wake of the shootings at Virginia Tech in 2007, Congress also created incentives for States to make as many relevant records as possible accessible to NICS. Over the past three years, States have increased the number of records they make accessible by nearly 70 percent. To further encourage this reporting, the Attorney General has written a letter to States highlighting the importance of receiving complete criminal history records and criminal dispositions, information on persons disqualified for mental health reasons, and qualifying crimes of domestic violence. The Administration will begin a new dialogue with States to ensure the background check system is as robust as possible, which is a public safety imperative.

- Make the background check system more efficient and effective. In 2015, NICS received more than 22.2 million background check requests, an average of more than 63,000 per day. By law, a gun dealer can complete a sale to a customer if the background check comes back clean or has taken more than three days to complete. But features of the current system, which was built in the 1990s, are outdated. The Federal Bureau of Investigation (FBI) will take the following steps to ensure NICS operates more efficiently and effectively to keep guns out of the wrong hands:

- o FBI will hire more than 230 additional NICS examiners and other staff members to assist with processing mandatory background checks. This new hiring will begin immediately and increase the existing workforce by 50 percent. This will reduce the strain on the NICS system and improve its ability to identify dangerous people who are prohibited from buying a gun before the transfer of a firearm is completed.

- o FBI has partnered with the U.S. Digital Service (USDS) to modernize NICS. Although NICS has been routinely upgraded since its launch in 1998, the FBI is committed to making the system more efficient and effective, so that as many background checks as possible are fully processed within the three-day period before a dealer can legally sell a gun even if a background check is not complete. The improvements envisioned by FBI and USDS include processing background checks 24 hours a day, 7 days a week to improve overall response time and improving notification of local authorities when certain prohibited persons unlawfully attempt to purchase a firearm.

## Making Our Communities Safer from Gun Violence

In order to improve public safety, we need to do more to ensure smart and effective enforcement of our gun laws and make sure that criminals and other prohibited persons cannot get their hands on lost or stolen weapons. The Administration is therefore taking the following actions:

- Ensure smart and effective enforcement of our gun laws. In a call earlier today, the Attorney General discussed the importance of today's announcements and directed the Nation's 93 U.S. Attorneys across the country to continue to focus their resources—as they have for the past several years under the Department's Smart on Crime initiative—on the most impactful cases, including those targeting violent offenders, illegal firearms traffickers, and dangerous individuals who bypass the background check system to acquire weapons illegally. During the call, the Attorney General also emphasized ongoing initiatives to assist communities in combating violent crime, including ATF's efforts to target the “worst of the worst” gun crimes. These efforts will also complement the following actions announced today:
  - o The President's budget for FY2017 will include funding for 200 new ATF agents and investigators who can help enforce our gun laws, including the measures announced today. Strategic and impactful enforcement will help take violent criminals off the street, deter other unlawful activity, and prevent guns from getting into the wrong hands.
  - o ATF is dedicating \$4 million and additional personnel to enhance the National Integrated Ballistics Information Network (NIBIN). The NIBIN database includes ballistic evidence that can be used by analysts and investigators to link violent crimes across jurisdictions and to track down shooters who prey on our communities. In February 2016, ATF is standing up the National NIBIN Correlation and Training Center—which will ultimately provide NIBIN matching services at one national location, rather than requiring local police departments to do that work themselves. The Center will provide consistent and capable correlation services, making connections between ballistic crime scene evidence and crime guns locally, regionally, and nationally. These enhancements will support ATF's crime gun intelligence and enforcement efforts, particularly in communities most affected by violent crime.
  - o ATF has established an Internet Investigations Center (IIC) staffed with federal agents, legal counsel, and investigators to track illegal online firearms trafficking and to provide actionable intelligence to agents in the field. The IIC has already identified a number of significant traffickers operating over the Internet. This work has led to prosecutions against individuals or groups using the “dark net” to traffic guns to criminals or attempting to buy firearms illegally online.

- Ensure that dealers notify law enforcement about the theft or loss of their guns. Under current law, federal firearms dealers and other licensees must report when a gun from their inventory has been lost or stolen. The regulations are ambiguous, however, about who has this responsibility when a gun is lost or stolen in transit. Many lost and stolen guns end up being used in crimes. Over the past five years, an average of 1,333 guns recovered in criminal investigations each year were traced back to a licensee that claimed it never received the gun even though it was never reported lost or stolen either. Today, ATF issued a final rule clarifying that the licensee shipping a gun is responsible for notifying law enforcement upon discovery that it was lost or stolen in transit.

- Issue a memo directing every U.S. Attorney's Office to renew domestic violence outreach efforts. In the event of an emergency, victims of domestic violence should call 911 or otherwise contact state or local law enforcement officials, who have a broader range of options for responding to these crimes. To provide an additional resource for state, local, and tribal law enforcement and community groups focused on domestic violence, the Attorney General is issuing a memo directing U.S. Attorney's Offices around the country to engage in renewed efforts to coordinate with these groups to help combat domestic violence and to prevent prohibited persons from obtaining firearms.

#### Increase Mental Health Treatment and Reporting to the Background Check System

The Administration is committed to improving care for Americans experiencing mental health issues. In the last seven years, our country has made extraordinary progress in expanding mental health coverage for millions of Americans. This includes the Affordable Care Act's end to insurance company discrimination based on pre-existing conditions, required coverage of mental health and substance use disorder services in the individual and small group markets, and an expansion of mental health and substance use disorder parity policies, all of which are estimated to help more than 60 million Americans. About 13.5 million more Americans have gained Medicaid coverage since October 2013, significantly improving access to mental health care. And thanks to more than \$100 million in funding from the Affordable Care Act, community health centers have expanded behavioral health services for nearly 900,000 people nationwide over the past two years. We must continue to remove the stigma around mental illness and its treatment—and make sure that these individuals and their families know they are not alone. While individuals with mental illness are more likely to be victims of violence than perpetrators, incidents of violence continue to highlight a crisis in America's mental health system. In addition to helping people get the treatment they need, we must make sure we keep guns out of the hands of those who are prohibited by law from having them. Today, the Administration is announcing the following steps to help achieve these goals:

- Dedicate significant new resources to increase access to mental health

care. Despite our recent significant gains, less than half of children and adults with diagnosable mental health problems receive the treatment they need. To address this, the Administration is proposing a new \$500 million investment to help engage individuals with serious mental illness in care, improve access to care by increasing service capacity and the behavioral health workforce, and ensure that behavioral health care systems work for everyone. This effort would increase access to mental health services to protect the health of children and communities, prevent suicide, and promote mental health as a top priority.

- Include information from the Social Security Administration in the background check system about beneficiaries who are prohibited from possessing a firearm. Current law prohibits individuals from buying a gun if, because of a mental health issue, they are either a danger to themselves or others or are unable to manage their own affairs. The Social Security Administration (SSA) has indicated that it will begin the rulemaking process to ensure that appropriate information in its records is reported to NICS. The reporting that SSA, in consultation with the Department of Justice, is expected to require will cover appropriate records of the approximately 75,000 people each year who have a documented mental health issue, receive disability benefits, and are unable to manage those benefits because of their mental impairment, or who have been found by a state or federal court to be legally incompetent. The rulemaking will also provide a mechanism for people to seek relief from the federal prohibition on possessing a firearm for reasons related to mental health.

- Remove unnecessary legal barriers preventing States from reporting relevant information to the background check system. Although States generally report criminal history information to NICS, many continue to report little information about individuals who are prohibited by Federal law from possessing or receiving a gun for specific mental health reasons. Some State officials raised concerns about whether such reporting would be precluded by the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Today, the Department of Health and Human Services issued a final rule expressly permitting certain HIPAA covered entities to provide to the NICS limited demographic and other necessary information about these individuals.

### Shaping the Future of Gun Safety Technology

Tens of thousands of people are injured or killed by firearms every year—in many cases by guns that were sold legally but then stolen, misused, or discharged accidentally. Developing and promoting technology that would help prevent these tragedies is an urgent priority. America has done this in many other areas—from making cars safer to improving the tablets and phones we use every day. We know that researchers and engineers are already exploring ideas for improving gun safety and the tracing of lost or stolen guns. Millions of dollars have already been invested to support research into concepts that range from fingerprint scanners to radio-frequency identification to microstamping

technology.

As the single largest purchaser of firearms in the country, the Federal Government has a unique opportunity to advance this research and ensure that smart gun technology becomes a reality—and it is possible to do so in a way that makes the public safer and is consistent with the Second Amendment. Today, the President is taking action to further this work in the following way:

- Issue a Presidential Memorandum directing the Department of Defense, Department of Justice, and Department of Homeland Security to take two important steps to promote smart gun technology.
  - o Increase research and development efforts. The Presidential Memorandum directs the departments to conduct or sponsor research into gun safety technology that would reduce the frequency of accidental discharge or unauthorized use of firearms, and improve the tracing of lost or stolen guns. Within 90 days, these agencies must prepare a report outlining a research-and-development strategy designed to expedite the real-world deployment of such technology for use in practice.
  - o Promote the use and acquisition of new technology. The Presidential Memorandum also directs the departments to review the availability of smart gun technology on a regular basis, and to explore potential ways to further its use and development to more broadly improve gun safety. In connection with these efforts, the departments will consult with other agencies that acquire firearms and take appropriate steps to consider whether including such technology in specifications for acquisition of firearms would be consistent with operational needs.

#### About AMWA:

The American Medical Women's Association (AMWA) is an organization that functions at the local, national, and international level to advance women in medicine and improve women's health. We achieve this by providing and developing leadership, advocacy, education, expertise and mentoring and through building strategic alliances. Founded in 1915, AMWA is the oldest multi-specialty organization of women physicians. As the vision and voice of women in medicine for nearly a century, AMWA empowers women to lead in improving health for all, within a model that reflects the unique perspective of women.

**February 02, 2016**— AMWA signs on Sign our petition with the 1,000 Days campaign urging Congress to support paid leave by passing the FAMILY Act. That's why the National Partnership is partnering with 1,000 Days to urge Congress to support the Family And Medical Insurance



Leave (FAMILY) Act — common sense legislation that would establish a national paid family and medical leave program that covers virtually everyone, no matter where they live or work.

- 80 percent of Americans say they support paid family leave;
- 203 business and management school professors have called on Congress to enact a national paid leave law;
- At least 20 major companies added or expanded paid leave policies in 2015 alone;
- Three states have paid family and medical leave insurance laws; and
- At least 24 localities have adopted paid family leave policies for city or county workers.

The Obama administration is paving the way for paid leave, but Congress has yet to act.

**[Sign our petition with the 1,000 Days campaign urging Congress to support paid leave by passing the FAMILY Act](#)**



**February 08, 2016**—AMWA signs on letter; Physicians for Reproductive Health is working with ACOG to file an amicus brief in the Affordable Care Act “accommodations” cases that are before the Supreme Court this term. These are the cases filed by religiously-affiliated non-profits who object to providing their employees with insurance coverage for contraception. The “accommodation” allows these employers to opt-out of the requirement by proving written notification to their insurer or to the federal government. The employer says that completing the required paperwork violates their religious freedom. Our brief will be quite similar to the brief that we filed in Hobby Lobby, and will demonstrate the importance of contraception to women and children’s health.

**February 14, 2016--** AMWA signs on letter; FDA’s 2013 Proposed Rule enabling manufacturers of generic drugs to update labeling on their products to reflect new patient safety information. The FDA generics labeling rule is an important step towards improving consumer safety and the rights of consumers within the generic drug market. The rule would allow generic drug manufacturers to unilaterally update their labels when new safety information becomes available. Almost a year ago, FDA held a public listening session on the proposed rule and re-opened the comment period. At the listening session, the proposed rule was supported by numerous stakeholders, including: patients, their families, multiple consumer groups, health groups, and health professionals.

February 29, 2016

The Honorable Sylvia Mathews Burwell  
United States Secretary of Health and Human Services

200 Independence Avenue  
Washington, DC 20201

Dear Secretary Burwell,

We are writing to urge the Obama Administration to move forward with finalizing the FDA's Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products (Docket No. FDA-2013-N-0500) rule.

As you know, the Food and Drug Administration (FDA) proposed regulations in 2013 to allow generic drug manufacturers to initiate safety, efficacy, and dosing updates to their products' labeling. We strongly supported the rule when it was first released. Nearly three years later, we see an even greater need for its completion.

Requiring all prescription drugs to carry up-to-date safety warnings is essential for improving the safety and efficacy of all FDA approved drugs as well as for shoring up needed consumer safeguards and protections. This essential rule will enable generic drug manufacturers to revise drug labeling through the changes-being-effected (CBE-0) process that brand-name manufacturers have used since the 1980s. Extending this process to generic drug manufacturers will give physicians, patients, and their family members access to better and more accurate information about the risks and benefits of the medications they are taking, regardless of whether a drug is brand-name or generic. Generic manufacturers currently are barred from updating product labeling with new warning information, except in response to a brand-name update or FDA order. But shortly after a generic enters the market, typically the brandname manufacturer precipitously loses market share and in many cases, the brand-name ceases production of the equivalent drug altogether. In fact, most prescription drugs sold in the United States are generics.

As a result, the current system's heavy reliance on brand-name manufacturers to initiate all labeling changes, even after generics enter the market, no longer makes sense. Both brand-name and generic drug manufacturers must have the ability to update drug labels expeditiously. Allowing generic manufacturers to initiate safety updates, as brand-name companies have done for 30 years, is essential for patients. As the Government Accountability Office reported in January: "FDA lacks reliable, readily accessible data on tracked safety issues and postmarket studies needed to meet certain postmarket safety reporting responsibilities and to conduct systematic oversight." The GAO findings only highlight the need for manufacturers—whether brand-name or generic—to have responsibility for the adequacy of product labeling. Promptly updated labeling allows physicians and patients to make better informed health decisions and can help prevent serious harm to patients.

Since the rule was first proposed, there have been attempts to delay or water down the rule. One alternative offered would go so far as to prevent brand-name manufacturers, in certain circumstances, from promptly updating safety information, again, as most prescription drugs sold in the United States have done since the 1980s. This proposal would represent a significant step backward for consumer safety.

Over 24,000 people have signed a petition asking FDA to move forward in finalizing the proposed rule, to ensure that all prescription medicines, including generic drugs, carry current and accurate safety warnings. We urge the Administration to ensure that the proposed rule regarding generic manufacturers' ability to initiate labeling updates is

finalized as soon as possible. Until then, millions of patients and families face unnecessary health risks.

Thank you for your consideration.

Sincerely,

National Center for Health Research

National Women's Health Network

Public Citizen

Food and Drug Administration  
Office of the Commissioner  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2013-N-0500, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products**

Dear Sir/Madam:

In November 2013, the Food and Drug Administration (FDA) proposed to revise its regulations to allow generic drug manufacturers to initiate safety, efficacy, and dosing updates to their products' labeling. We strongly supported the FDA's *Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products* when it was released, and we strongly support the rule moving forward expeditiously through the regulatory approval process now.

Requiring all prescription drugs to carry up-to-date safety warnings is essential for improving the safety and efficacy of all FDA approved drugs as well as for shoring up needed consumer safeguards and protections. This new rule will enable generic drug manufacturers to revise drug labeling through the changes-being-effected (CBE-0) process, which currently permits brand-name manufacturers to update product labeling subject to simultaneous (instead of prior) review by the FDA. Extending this process to generic drug manufacturers will give physicians, patients, and their family members access to better and more accurate information about the risks and benefits of the medications they are taking, regardless of whether a drug is brand-name or generic.

Generic manufacturers currently are barred from providing new warning information, except in response to a brand-name update or FDA order. Most prescription drugs sold in the United States, however, are generic versions, and the brand-name manufacturer sometimes stops selling a drug after generic versions come on the market. The current system, which depends almost exclusively on brand-name manufacturers to maintain pharmacovigilance, no longer makes sense. Both brand-name and generic drug manufacturers must have the ability and duty to update drug labels expeditiously. Allowing generic manufacturers to initiate safety updates, as brand-name companies have done for 30 years, is essential for patients. Promptly updated warning labeling allows physicians and patients to make better informed health decisions and can help prevent serious harm to patients.

AMWA will publish this information in its newsletter, on twitter, and other social media.

Feb 17, 2016 AMWA signs onto Brief of Amici Curiae of American College of Obstetricians and Gynecologists, Physicians for Reproductive Health American Academy of Family Physicians, American Nurses Association, et al in Support of the Government and Affirmance. <https://www.amwa-doc.org/wp-content/uploads/2017/04/ACOG-et-al-amicus-brief-Zubik.pdf>

March 2016 AMWA signs onto provider letter in support of the EACH Woman Act  
Dear Members of Congress:

As organizations that represent health care providers and public health professionals who strive to improve the health of women and families across the country, we write in support of the Equal Access to Abortion Coverage in Health Insurance (EACH Woman) Act of 2015 (HR 2972).

The EACH Woman Act improves access to reproductive health care by ensuring that every woman who receives care or insurance through the federal government will have coverage for abortion care and by prohibiting political interference in private health insurance company policies that offer coverage for abortion care. Safe, legal abortion is a necessary component of women's health care. One in three women will have an abortion by the age of 45, and every woman should have access to health insurance that covers a full range of medical procedures, including abortion, without additional administrative or financial burdens.

As health care professionals, we are deeply concerned with the increasing number of restrictions on access to affordable health coverage and access to abortion care, both at the federal and state level. Abortion is an integral component of women's health care and our patients need insurance coverage that meets their medical needs. The EACH Woman Act would improve access to abortion care by eliminating abortion coverage bans for low-income women who qualify for Medicaid. It would also ensure abortion coverage is available to federal employees and their dependents; military personnel, veterans, and their families; women with disabilities enrolled in Medicare; adolescents in the Children's Health Insurance Program; Native American and Alaska Native women; Peace Corps volunteers; federal prison inmates; and women in federal detention centers.

Withholding insurance coverage for abortion care imposes profound hardships for millions of women and families, particularly for those who may already face significant barriers to accessing health care, including low-income women, young women, immigrant women, and women of color. As a community of health care providers, we work hard to provide high-quality health care to our patients. Raising money for an abortion can mean delaying care, which raises the cost and complexity of the procedure, or not obtaining care at all. Twenty to thirty-five

percent of Medicaid-eligible women who would choose abortion carry their pregnancies to term when public funds are not available.<sup>1</sup> Regulations like insurance bans that unfairly impose burdensome requirements to accessing abortion interfere with the patient-provider relationship and undermine our patients' health.

At a time when we are seeing increased attacks on access to health care and abortion care, we need our legislators to stand up for reproductive health and support the EACH Woman Act. We need a federal law that protects all of our patients' access to reproductive health care, including abortion, regardless of where they live or what type of insurance they carry.

Sincerely,

[List in Formation]

Heather Boonstra and Adam Sonfield, "Rights Without Access: Revisiting Public Funding of Abortion for Poor Women," The Guttmacher Report on Public Policy vol.3(2) (April 2000) (available at <http://www.guttmacher.org/pubs/tgr/03/2/gr030208.html>).

March 21, 2016 AMWA signs on to letter supporting the Proposed Rule on the Restricted Sale, Distribution, and Use of Sunlamp Products <https://www.amwa-doc.org/wp-content/uploads/2017/04/March-21-Sunlamp-Restrictions-draft-final.pdf>

March 21, 2016

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Comments on Proposed Rule  
Restricted Sale, Distribution, and Use of Sunlamp Products  
[Docket No. FDA-2015-N-1765]

As members of the Patient, Consumer, and Public Health Coalition, we strongly support the proposed rule that bans minors (individuals under the age of 18) from using commercial tanning beds (sunlamp products). However, we think the age limit should be 21, as it is for alcohol, and as it is for cigarettes in more than 100 U.S. cities. [1]

In 2013, our coalition submitted comments to the FDA recommending that the agency upclassify sunlamp devices from Class I (low risk devices) to Class III (high risk devices).[2] Unfortunately, the agency only up-classified the device to

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Class II (moderate risk devices). Now, in its proposed rule, the FDA cites studies that the devices are directly correlated to skin cancer including the most deadly form, melanoma. Since there are virtually no medical benefits to using commercial tanning beds and the World Health Organization's (WHO) International Agency for Research on Cancer (IARC) classified indoor tanning devices as carcinogenic to humans, [3] we recommend that FDA ban the devices entirely (not just for users under age 18). At the very least the FDA should ban the devices for users under 21 and reclassify sunlamp 2 products as Class III (high risk devices). High-risk devices are ones that can cause substantial harm or even death, and clearly, sunlamps satisfy those criteria.

In the meantime, however, we support the requirement that adult users of indoor tanning salons sign a risk acknowledgment certificate, and the proposed rule's requirement that user manuals be provided by salon staff to other staff and any customer who asks for one.

Below are our specific comments on the proposed rule.

### **Age Restrictions on Tanning Devices**

Young people, especially women (who use the devices more often than young men), are extremely vulnerable to the health risks of tanning devices. Using indoor tanning beds before age 35 can increase the risk of melanoma—the deadliest form of skin cancer—by 59%. [4] The risk increases with the number of sunbed sessions and is higher if the person begins using tanning devices at a younger age. [3] Medical evidence points to a “direct correlation between sunlamp product use among youths and their developing melanoma skin cancer.” [5] Melanoma is a leading cause of cancer death in women ages 15 to 29 years.[5] In 2013, the American Cancer Society (ACS) estimated 76,690 new cases of melanoma in the United States and 9,480 deaths from the disease during the year.<sup>6</sup> Each year, approximately 400,000 cases of skin cancer (including melanoma) in the U.S. are caused by indoor tanning, according to the American Academy of Dermatology.[4]

A recent study showed that restrictions on access to tanning beds will reduce the number of young people using them. Female high school students in states with indoor tanning laws were less likely to engage in indoor tanning compared to students in states without any laws, according to the Centers for Disease Control and Prevention. [7]

The FDA's proposed rule banning use by minors under 18 will reinforce regulatory actions already taken by more than 40 states. Minors are banned from using commercial tanning beds in 11 states (California, Delaware, Illinois, Louisiana, Minnesota, Nevada, New Hampshire, North Carolina, Oregon, Texas, and Vermont) and the District of Columbia. <sup>6</sup> Just this month, Kansas House lawmakers overwhelmingly passed a bill to ban minors from indoor tanning salons and the legislation has been sent to the state Senate. [8]

The FDA's proposed rule will protect minors in all states, but only under the age of 18. The cancer damage associated with sun tanning devices is substantial and could be avoided by stricter regulations.[3] The FDA's proposed rule dovetails with recommendations from the IARC, which stated: "Policymakers should consider enacting measures, such as prohibiting minors and discouraging young adults from using indoor tanning facilities, to protect the general population from possible additional risk for melanoma." [9]

We strongly support the proposed rule that would ban minors from using the devices and agree with the FDA that "by restricting sunlamp product use to individuals 18 and older, we would be protecting a subpopulation that generally tends to discount risk information and favor risk taking." [5] Unfortunately, however, young adults over 18 also tend to ignore risk information. [3] There is no logical reason to have an age limit of 18 for sunlamps, when the age limit is 21 for alcohol and tobacco products in more than 100 U.S. cities.

### **Prospective Users Signing Risk**

**Acknowledgement Certificates** The proposed rule does not go far enough in protecting those 18 and older when it requires the owners of tanning salons to have those users sign a risk acknowledgement statement, which is supposed to counteract any false or misleading information about the devices. However, without an effective enforcement or monitoring policy established, it is unlikely tanning salon owners will comply with this part of the proposed rule. Congress found in 2012 that tanning salons were providing "false and misleading Information" to customers. Congress also found that 90 percent of operators stated to customer inquiries "that indoor tanning presented no risks." [5]

### **Providing Sunlamp Product User Manuals**

Until sunlamps are either tested as PMA devices or banned entirely, we support requiring that the user manuals for the devices be provided to anyone who requests them. However, this protection is too weak. The manuals should be provided by salon staff within 5 minutes of a request and the FDA should not allow the salon operator to merely provide the address of the manufacturer/distributor or the address of the 510(k) holder). The reason is simple: those two options greatly delay the availability of the information that clients need to make an informed choice. In addition, it puts a burden on clients who request information that could save their lives, rather than putting the onus on the tanning salon to provide information needed for informed consent regarding the use of dangerous devices. Getting information from the manufacturer or distributor will inevitably take days, weeks, or months to receive.

Getting the information from a 510(k) holder is completely ludicrous even assuming that person's name and address can be accurately provided. The National Center for Health Research conducted a study on publicly available information regarding 510(k) medical devices and the Center found that the



addresses provided were frequently out of date. Moreover, although the companies were required by law to provide information upon request, only 20% of the 510(k) holders provided the requested information in unredacted form. [10]

## **Conclusion**

We strongly support the FDA's proposed rule to ban the use of commercial tanning devices by minors. This would reduce the risk of skin cancer for many Americans. However, since the FDA has not required that sunlamps be carefully studied through the PMA process, **we recommend that the FDA go even further to protect the public health by banning commercial sunlamp products entirely.**

American Medical Women's Association  
Cancer Prevention and Treatment Fund  
MISSD  
MRSA Survivors Network  
National Physicians Alliance  
Our Bodies Ourselves  
Washington Advocates for Patient Safety  
WoodyMatters

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or at [pb@center4research.org](mailto:pb@center4research.org)

[1] Sandrick, B (December 8, 2015). More than 100 U.S. Cities Raise Smoking Age to 21. Cleveland.com  
[http://www.cleveland.com/metro/index.ssf/2015/12/cleveland\\_follows\\_growing\\_nati.html](http://www.cleveland.com/metro/index.ssf/2015/12/cleveland_follows_growing_nati.html)

[2] Patient, Consumer, and Public Health Coalition (August 7, 2013). Comments on Proposed Order on "Reclassification of Ultraviolet Lamps for Tanning, Henceforth To Be Known as Sunlamp Products. Docket No. FDA-2013-N-0461.

[3] BMJ (2012). Boniol M, et al. Cutaneous melanoma attributable to sunbed use: systematic review and metaanalysis. <http://www.bmj.com/content/345/bmj.e4757>

[4] American Academy of Dermatology web page.

<https://www.aad.org/advocacy/skin-cancer-and-indoortanning/stop-skin-cancer>

[5] Federal Register (Tuesday, December 22, 2015). Proposed rule: General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products.

[6] National Conference of State Legislatures. Web page: Indoor Tanning Restrictions For Minors – A State-By-State Comparison.

<http://www.ncsl.org/research/health/indoor-tanning-restrictions.aspx>

[7] Centers for Disease Control and Prevention (2014). Press Release: Rates of indoor tanning among female high school students lowest in states with multiple restrictions on youth access. <http://www.cdc.gov/media/releases/2014/p0213-indoor-tanning.html>

[8] Associated Press (March 10, 2016). Lawmakers vote to ban Kansas minors from indoor tanning. Reported in the Kansas City Star.

<http://www.kansascity.com/news/state/kansas/article65208207.html>

[9] World Health Organization(WHO), International Agency for Research on Cancer (2006). Exposure to Artificial UV Radiation and Skin Cancer.

[10] Zuckerman, D, Brown, P, and Das A (2014) Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices. JAMA Intern Med.

March 28, 2016 AMWA signs on with the Patient, Consumer, and Public Health Coalition comments on the Proposed Order Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses [Docket No. FDA-2014-N-1210]. The Coalition opposes the split classification of electroconvulsive (ECT) devices. This reclassification would make ECT devices used for treatment-resistant major depression or depression requiring a rapid response class II (special controls) and all other psychiatric indications class III. <https://www.amwa-doc.org/wp-content/uploads/2017/04/March-28-Coalition-ECT-comment.pdf>

March 28, 2016

The Patient, Consumer, and Public Health Coalition comments on the Proposed Order Reclassification of Electroconvulsive Therapy Devices Intended for Use in Treating Severe Major Depressive Episode in Patients 18 Years of Age and Older Who Are Treatment Resistant or Require a Rapid Response; Effective Date of Requirement for Premarket Approval for Electroconvulsive Therapy for Certain Specified Intended Uses [Docket No. FDA-2014-N-1210]

As members of the Patient, Consumer, and Public Health Coalition, we are writing to strongly oppose the split classification of electroconvulsive (ECT) devices. This reclassification would make ECT devices used for treatment-resistant major depression or depression requiring a rapid response class II (special controls) and all other psychiatric indications class III.

An ECT device applies a brief intense electrical current to a patient's head to intentionally induce a major motor seizure.[1] These devices have only short-term benefits and are known to have serious risks and should only be used when the benefits are likely to outweigh the risks. That requires clinical trials, inspections, and other safeguards that are part of the PMA review process. Allowing any ECT devices to be cleared by the FDA through the 510(k) process for any indication puts patients at risk.

ECT can cause cardiac complications, prolonged or delayed onset seizures, and death.[2] This risk for harm is not any less when the devices are used to treat depression versus other psychiatric diagnoses. Eleven of the 14 risks identified by

the FDA would be mitigated exclusively by labeling. However, it is widely known that many doctors do not read the labels on devices carefully, if at all.

Even when the labeling and other controls are followed, the current treatment protocols for ECT devices still carry substantial risks for patients' cognitive impairment.[3,4,5] Studies demonstrate that the percentage of patients with complaints about ongoing memory problems even years after treatment ranges from 29 % to 67%. [6,7,8] These memory deficits greatly affect patients' lives, and an unknown proportion of these patients suffer very severe, persistent memory problems.[9,10,11,12] Unfortunately, the percentage of patients who suffer severe memory problems is unknown because the FDA has not required such research. It is not possible to predict the extent to which patients will be affected by a given device and protocol or which patients will develop severe memory problems.[13,14]

It would be very dangerous to patients if new ECT-like devices are approved without clinical trials. The strength of the current or voltage, as well as the length, pattern and waveform of the pulse affect the effectiveness and the extent of cognitive impairment. 14,15 For example, cognitive impairments are less severe when a brief pulse or ultrabrief pulse is used as opposed to a sine wave because less energy is required to induce a seizure.

Once an ECT device is cleared as a 510(k) class II device, it would serve as a predicate for many other potentially dangerous devices. In addition, if an ECT device can be cleared through the 510(k) process, device manufacturers have no incentive to apply for approval through the PMA process. To pretend otherwise is fundamentally dishonest, since the devices could be used offlabel for treatment of indications other than depression. The only way to ensure that the benefits outweigh the risks for any indication for which it is approved is to require a PMA review for these obviously high-risk devices.

In conclusion, ECT devices are potentially high-risk devices and should remain as class III and should be subject to PMA review for all indications. The risks for patients associated with down classification of ECT devices for depression greatly outweigh any presumed benefit.

American Medical Women's Association  
Connecticut Center for Patient Safety  
MISSD  
National Organization for Women  
National Women's Health Network  
The TMJ Association  
Washington Advocates for Patient Safety  
WoodyMatters

The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of millions of patients, consumers, health-care professionals, scientists, and public health experts. The coalition can be reached through Stephanie Fox-Rawlings, Ph.D. at [sfr@center4research.org](mailto:sfr@center4research.org) or (202) 223-4000.

[1] Code of Federal Regulations Title 21 Sec. 882.5940, "Electroconvulsive therapy device."

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=882.5940>

[2] Code of Federal Regulations, 21CFR882.5940. Identification of Electroconvulsive therapy device.

[3] Sackeim HA. (2014). Autobiographical memory and ect: don't throw out the baby. *J ECT* 30(3): 177–186. 4

[4] Tor PC, Bautovich A, Wang MJ, Martin D, Harvey SB, Loo C (2015). A systematic review and meta-analysis of brief versus ultrabrief right unilateral electroconvulsive therapy for depression. *J Clin Psychiatry* 76(9):e1092-8.

[5] Verwijk E, Comijs HC, Kok RM, Spaans HP, Stek ML, Scherder EJ. (2012). Neurocognitive effects after brief pulse and ultrabrief pulse unilateral electroconvulsive therapy for major depression: a review. *J Affect Disord* 140(3):233-43.

[6] Chakrabarti S, Grover S, Rajagopal R (2010). Electroconvulsive therapy: a review of knowledge, experience and attitudes of patients concerning the treatment. *World J Biol Psychiatry* 11(3): 525-537.

[7] Sienaert P1, De Becker T, Vansteelandt K, Demyttenaere K, Peuskens J. (2005). Patient satisfaction after electroconvulsive therapy. *J ECT* 21(4):227-31.

[8] Rose D, Fleischmann P, Wykes T, Leese M, Bindman J. (2003). Patients' perspectives on electroconvulsive therapy: systematic review. *BMJ* 326:1363.

[9] [www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFMcfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFMcfm) Manufacturer and User Facility Device Experience (MAUDE) Database.

[10] Smith M, Vogler J, Zarrouf F, Sheaves C, Jesse J. (2009). Electroconvulsive therapy: the struggles in the decision-making process and the aftermath of treatment. *Issues Ment Health Nurs* 30:554–559

[11] Vamos M (2008). The cognitive side effects of modern ECT: patient experience or objective measurement? *J ECT* 24: 18-24.

[12] Donahue AB.(2000) Electroconvulsive therapy and memory loss: a personal journey. *J ECT* 16(2): 133-143.

[13] Donel M. Martin, Verònica Gálvez, Colleen K. Loo (2015). Predicting retrograde autobiographical memory changes following electroconvulsive therapy: relationships between individual, treatment, and early clinical factors. *Int J Neuropsychopharmacol* 18(12): pyv067.

[14] McClintock SM, Choi J, Deng ZD, Appelbaum LG, Krystal AD, Lisanby SH. (2014). Multifactorial determinants of the neurocognitive effects of electroconvulsive therapy. *J ECT* 30:165-176.

[15] Prudic J (2008). Strategies to minimize cognitive side effects with ECT: aspects of ECT technique. *J ECT* 2008;24:46-51.

April 6, 2016 AMWA Executive Director, Dr. Eliza Chin, participates in press conference with leaders from Doctors for America and other health organizations on gun violence prevention and the need for increased federally funded research on gun violence. Together, over 100 medical and public health organizations called on Congress for federal gun research.

April 12, 2016 AMWA signs on to letter opposing the proposed rule (Federal Register Docket #2016-03722) based on President Obama's Executive Order 13706, Establishing Paid Sick Leave for Federal Contractors, which requires that employees that work on federal contracts are entitled to earn at least seven days or 56 hours of paid sick leave per year. <https://www.amwa-doc.org/wp-content/uploads/2017/04/April-12-Establishing-Paid-Sick-Leave-for-Federal-Contractors-Comment-March-10-sfr.pdf>

April 12, 2016

Establishing Paid Sick Leave for Federal Contractors

Proposed Rule RIN 1235-AA13 [Docket No. 2016-03722]

The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of patients, consumers, health-care professionals, scientists, and public health experts. As members of the coalition, we strongly support the proposed rule (Federal Register Docket #2016-03722) based on President Obama's Executive Order 13706, Establishing Paid Sick Leave for Federal Contractors, which requires that employees that work on federal contracts are entitled to earn at least seven days or 56 hours of paid sick leave per year.

The federal government provides paid sick leave to its employees, but not those who work indirectly for the federal government as contractors. This rule would extend sick leave for an estimated 828,000 employees, including providing paid sick leave for the estimated 437,000 that currently do not receive any. Currently, these men and women must choose between getting a pay check (and possibly retaining their job) and taking the time off to recover from an illness, get preventative care, or care for a family member.

Paid sick leave improves health and productivity of employees. It enables those who have physical or mental illnesses to take the time to recover when sick, to get preventative care, to deal with injuries, and to care for sick or injured family members. At the same time, it reduces the chances that their work colleagues will become sick as a result of their contagious illnesses. For all those reasons it results in greater productivity in the work place. Paid sick leave improves community health as well. Employees that cannot afford to take an unpaid sick day unwillingly expose co-workers, clients, and even those they are in contact with on public transportation or other public places to their illness. When employees' ill children cannot stay home from school, they also expose classmates. Enabling employees to stay home when sick reduces the transmission of illnesses throughout the community.

Providing paid sick leave also helps employers. Besides reducing productivity loss due to the spread of illness through the workforce and “presenteeism” losses[1,2], research shows that paid sick leave increases employee retention and overall productivity[3] . It also reduces the likelihood of workplace injuries[4] . The benefits of paid sick leave for communities are well established and currently 5 states, 22 cities, and one county have passed laws requiring paid sick leave. A study of six of these jurisdictions found that these laws have not hurt most businesses in the region nor the local economy[5].

In conclusion, paid sick day policies like those in the Department of Labor's proposed rule will save employers, taxpayers and families money, and promote healthier workplaces and communities. We urge you to proceed with implementation without delay.

American Medical Women’s Association  
Annie Appleseed Project  
Breast Cancer Action  
MISSD  
MRSA Survivors Network  
National Center for Health Research  
National Consumers League  
National Organization for Women  
National Women’s Health Network  
Our Bodies Ourselves  
Washington Advocates for Patient Safety  
WoodyMatters

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or [pb@center4research.org](mailto:pb@center4research.org)

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[www.nationalpartnership.org/researchlibrary/work-family/psd/paid-sickdays-low-cost-high-reward.pdf](http://www.nationalpartnership.org/researchlibrary/work-family/psd/paid-sickdays-low-cost-high-reward.pdf)

April 12, 2016 AMWA writes letter in support of a Los Angeles City Wide paid sick days law. Council File 14-1731- Follow-up Policy Elements for a Citywide Minimum Wage

April 12, 2016

Los Angeles Economic Development Committee  
c/o Office of the City Clerk  
200 N. Spring St., Room 470  
Los Angeles, CA 90012

*Attn: Adam Lid, Legislative Assistant*

Re: Council File 14-1731- Follow-up Policy Elements for a Citywide Minimum Wage

Honorable Councilmembers,

We strongly support a Los Angeles citywide paid sick days law. As a health provider association, we recognize the critical importance of paid sick time for the public health. When workers are able to take the time they need to recover from illness or care for a sick family member, we can limit the spread of communicable diseases, improve workers' productivity, and boost our economy.

The American Medical Women's Association is an organization which supports the advancement of women in medicine and women's health. This issue is important to the health of women in this country.

Considerable research indicates that lack of paid sick days contributes to the spread of flu and other illnesses. Particularly for workers handling food or working with vulnerable populations, such as patients in healthcare settings, children, and the elderly, the dangers of working while ill extend well beyond the individual worker to whole communities. Moreover, research shows that when parents have access to paid sick days, they are more likely to ensure their children receive critical vaccinations, and children are more likely to recover quickly from illness when they are cared for by their parents. Workers with sick days are more likely to receive regular well-care, cancer screenings, and prenatal care.

Thanks to recent healthcare reforms, a millions more Californians now have access to health insurance. But in order for Angelenos to reap the benefits of their new coverage, including access to the preventive care that will ultimately save our economy billions of dollars, they must have the time to visit their healthcare providers without fear of losing their jobs or their wages.

The nation's leading public health organization, the American Public Health Association (APHA), has voiced [strong support](#) for laws that guarantee workers access to paid sick time. In the absence of federal law, the APHA has urged states and localities to pass their own paid sick days laws, pointing to San Francisco's law as a model. While the state of California has recently passed its own law, the maximum of three days it guarantees workers lags behind what San Francisco guarantees its workers: up to nine days. We must ensure that workers in Los Angeles catch up to their counterparts in San Francisco, Emeryville, Oakland, and now in our neighboring city, Santa Monica.

The Los Angeles City Council has exercised impressive leadership in passing a \$15 minimum wage; this is an important step that will lift many families out of poverty. Yet, according to one study, one in seven low-wage workers – and one in five low-wage working mothers – has lost a job in the past four years because they were sick or need to care for a family member. If workers risk losing their jobs simply because their children have the flu or they must see a doctor, even a higher minimum wage will not be enough to ensure they can support their families.

I respectfully ask that the committee support a strong local paid sick days law without delay. It is essential for a healthy Los Angeles.

Sincerely,



Eliza Lo Chin, MD, MPH  
Executive Director  
American Medical Women's Association

April 28, 2016 AMWA joins the Patient, Consumer, and Public Health Coalition to provide comments on the "National Direct-to-Consumer Advertising Survey Docket No. FDA-2016-N-0544. <https://www.amwa-doc.org/wp-content/uploads/2017/04/Coalition-Comments-on-DTC-Survey-April-2016.pdf>

April 29, 2016  
Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Maryland 20852

**Comments of members of the Patient, Consumer, and Public Health Coalition on the "National Direct-to-Consumer Advertising Survey Docket No. FDA-2016-N-0544**



As members of the Patient, Consumer, and Public Health Coalition, we appreciate the opportunity to comment on the “National Direct-to-Consumer Advertising Survey.” In general, we support this survey, which will update information from surveys completed in 1999 and 2002.

The objective of this research is to gain information from the public about “their experiences with and attitudes toward direct-to-consumer (DTC) advertising of prescription drugs.”<sup>1</sup> Topics covered by the survey include consumer’s knowledge of FDA’s authority over DTC ads, how often they’re exposed to DTC ads, their beliefs and attitudes about DTC ads and the influence of DTC advertising on patient-doctor interactions. The survey will measure other characteristics such as demographics, insurance coverage, and prescription drug use. We want to make sure that the questions about beliefs and attitudes will include gathering information about consumers’ views on how information about the benefits and risks is provided, if it could be provided in a more unbiased way, and how it influences their views of the product being advertised. Ideally, you can provide short DTC videos for respondents to watch and ask them questions about what benefit-risk information they recall from those ads.

The new study of DTC ads is designed to reach a wider range of respondents than the previous surveys by weighting the data to make it nationally representative. We agree that the survey should represent the demographic makeup of the United States in sufficient numbers to analyze subgroups based on race, ethnic backgrounds, and sex. The survey should be skewed to include a disproportionate number of Americans over 50, since they are the target of vast majority of DTC ads and are also the most likely to be exposed to those ads on TV and in magazines. Of course, younger adults (18 and over) should also be included. Ideally, the study would include a sufficient number of teenagers who are 14-18 years old, to gather meaningful information about that age group.

We agree with the FDA that the DTC advertising landscape has changed since the previous surveys. We are concerned that extremely brief social media ads will not include sufficient information about risks. Since DTC ads focus primarily on selling products, it is unacceptable for the risks of a product to be listed through a link that consumers may not click or the often-used phrase, “for more information, see this month’s issue” of a particular magazine. The survey should directly ask respondents how much information about the risks of the medical products they notice from social media ads.

Regarding the survey procedures, we support the mixed-mode methodology where households will be asked to complete a 20-minute online survey with a paper questionnaire sent to those who do not respond on-line. The paper option will ensure that respondents who are not internet savvy will still be included. The survey is designed to have as many as five contacts sent by mail to adults aged 18 and older and this should ensure that the FDA achieves at least its 35 percent response rate for both the pilot study and the main study. These estimated

response rate percentages are lower than the telephone surveys conducted in 1999 (65 percent or 960 respondents) and in 2002 (53 percent or 944 respondents)[2] but the total number of respondents (1,765) is estimated to be higher for the new survey.

FDA also plans to compare responses between this survey and FDA's 2002 survey. In 2002, "60 percent [of respondents] felt that ads do not provide enough information about risks." [2] That is a high percentage. We want to know if that percentage has gone up or down, and what steps FDA and industry are taking to provide more information about the risks of medical products. We are particularly interested in the number of people searching the internet for drug and health information, which jumped from 18 percent in 1999 to 38 percent in 2002. Back then, most people were looking for information about risks associated with the medical products. [2] The new survey should ask people how often they search the internet regarding medical products and what information they are inquiring about.

### **Conclusions**

We are very concerned about the impact of DTC ads on prescriptions, and are especially disappointed at the FDA's failure to follow through on the agency's previous proposals to put risk information on a more equal footing with information about benefits. Due to the FDA's continued acquiescence to companies' proposed ads, DTC ads use the power of an expensive advertising campaign to persuade patients to use medical products that may not be safe or appropriate for them. Rather than empowering consumers, direct-to-consumer ads expose consumers to the most effective persuasion that money can buy. To truly protect consumers, and reduce unnecessary healthcare costs, Congress and the FDA need to do more than survey the public about DTC ads. They need to propose laws and rules to limit the persuasive power and unbalanced information provided in DTC ads, especially for drugs that have not been tested for long-term safety on a large population.

American Medical Women's Association  
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National Women's Health Network  
Quinolone Vigilance Foundation  
The TMJ Association  
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The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of millions of patients, consumers, health-care professionals, scientists, and public health experts. The coalition can be reached through Paul Brown at (202) 223-4000 or at [pb@center4research.org](mailto:pb@center4research.org).

[1] Federal Register (February 29, 2016). Food and Drug Administration, Agency Information Collection Activities; Proposed Collection: Comment Request; National Direct-to Consumer Advertising Survey.

[2] Food and Drug Administration (November 19, 2004). Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs —Summary of FDA Survey Research Results, Final Report.

April 29, 2016 AMWA joins the Patient, Consumer, and Public Health Coalition to support the FDA's Efforts to Improve Diversity and Analyses in Clinical Trials. Docket No. FDA-2015-N-4952. <https://www.amwa-doc.org/wp-content/uploads/2017/04/PCPHC-comments-on-subgroups-April-2016.pdf>

April 29, 2016  
Division of Dockets Management  
Food and Drug Administration  
5630 Fishers Lane, Room 1061 (HFA-305)  
Rockville, Maryland 20852

**Comments of members of the Patient, Consumer, and Public Health Coalition on FDA's Efforts to Improve Diversity and Analyses in Clinical Trials Docket No. FDA-2015-N-4952**

We are writing as member organizations of the Patient, Consumer, and Public Health Coalition, to express our views on the need for diversity and subgroup analyses in clinical trials.

We support efforts to improve the safety and effectiveness of drugs and medical devices for ALL patients that are likely to use them. Women, people of color, and patients over the age of 65 have often been under-represented in clinical trials. Just as that was improving in recent years, efforts to speed drug approval have resulted in smaller clinical trials. So, the numbers of patients in those groups are again shrinking, making it impossible to do meaningful analysis of safety or effectiveness.

For example, cancer is most common in the elderly, but many cancer drug trials include very few elderly patients. Cancer drugs are often more toxic and less effective in the elderly. But with so little information on elderly patients when a drug is approved, it can be years later that we learn that elderly patients are more likely to be harmed if approved dosing information is followed.

The National Center for Health Research recently examined drugs reviewed by FDA Advisory Committees in 2014. They found that, for the 24 drugs the committees reviewed, 7 sponsors did not even tell FDA how many patients in their studies were 65 and older. That is a crucial subgroup for Medicare to make coverage decisions, and should always be analyzed separately. An additional 2 sponsors included fewer than 30 patients 65 and older. In other words, over one-third of the drugs were not studied on enough patients over 65 to draw even the most preliminary conclusions about safety or efficacy.

Similarly, over a quarter of the drugs did not include at least 30 African Americans – some didn't even include 10! It is impossible to conduct meaningful subgroup analyses with such a small number of patients.

And although women were always included when appropriate, 23% of drugs did not include a subgroup analysis to determine if the drug was safe for women.

Here's one egregious example. FDA did not require subgroup analysis of Blacks when the company submitted clinical trials for Singulair for asthma in 2014, despite previous evidence that the drug did not work for Blacks.

**The FDA should make it clear that the agency will not approve medical products for all populations if meaningful subgroup analysis for safety and effectiveness were not conducted for major demographic groups.**

We do not believe that the major impediment to diversity in clinical trials is the lack of interest of women, people of color, or patients over 65. Inconvenient locations are a major impediment, however. Companies have not done a better job of recruiting because they know FDA will approve their drugs even when adequate subgroup analyses are not conducted.

In the same way that companies recruit the best possible physicians by providing generous incentives to participate in clinical trials, companies should do the same to make participation in clinical trials possible and affordable (and even attractive) for patients of limited financial means or with limited resources.

Most important, the FDA needs to make it clear to companies that if they want their drugs approved for women and men, whites and people of color, and adults of all ages (and especially Medicare beneficiaries), they need to study sufficient numbers of those patients in subgroup analyses to make sure the drugs are safe and effective for them in the short-term and long-term.

American Medical Women's Association  
Annie Appleseed Project  
Breast Cancer Action  
Breast Cancer Consortium

Center for Medical Consumers  
National Center for Health Research  
National Organization for Women Foundation  
Our Bodies Ourselves  
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WoodyMatters

*The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of millions of patients, consumers, health-care professionals, scientists, and public health experts. The coalition can be reached through Tracy Rupp at (202) 223-4000 or at [tr@center4research.org](mailto:tr@center4research.org)*

May 24, 2016 AMWA signs on to letter opposing federal regulations to speed the development and approval of new medical products. <https://www.amwa-doc.org/wp-content/uploads/2017/04/Innovations-Ltr.pdf>

May 24, 2016  
The Honorable #{Fname} #{Lname}  
United States Senate  
Washington, DC 20510

Dear Senator #{Lname},

A recent STAT-Harvard poll shows that a majority of Americans oppose changing federal regulations to speed the development and approval of new medical products. They are concerned that speeding approvals would lower safety and effectiveness standards for medical products.[1] As members of the Patient, Consumer, and Public Health Coalition, we share those concerns. We also write to emphasize that any effort to develop safe and effective medical products should include mandatory new funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA).

The House's 21st Century Cures Act and its Senate companion legislation should focus more on ensuring that medical products are safe and effective and less on speeding medical products to the market. We appreciate that the Senate bills were less dangerous for patients than the House legislation. But, we opposed 6 of the 19 bills that the Senate passed out of the HELP Committee because they were not beneficial to patients.

When these bills (which we've listed below) reach the Senate floor, we strongly urge you to oppose them because they weaken FDA's safety and effectiveness standards.

Current and former FDA Commissioners have expressed their concerns as well. Current FDA Commissioner, Robert Califf recently said, "This legislation, if not

carefully crafted, could pose significant risks for FDA and American patients...Innovative therapies are not helpful to patients if they don't work, or worse, cause harm.”[2] Former FDA Commissioner David Kessler, who in the 1990s led the FDA under presidents from both parties, said, “It’s time to uncouple the promise of research funding from the requirement that FDA standards be lowered.”[2]

The underlying premise of the House and Senate bills seems to be that the FDA needs to speed up its approval process. This premise is based on the erroneous claim that other countries approve medical products more quickly. Nearly two-thirds of the novel drugs approved in 2015 (29 of 45, 64%) were approved in the United States before being approved in any other country.[3] In fact, a Forbes article expressed concern that the pendulum has swung too far and that “the FDA is basically providing a rubber stamp” for drug approvals and that drug approvals are at an all-time high.[4]

Similarly, research indicates that “it takes the same amount of time or less for patients to gain access to innovative, high-risk medical devices” in the U.S. as compared to Germany, France, Italy, and Britain.[5] Approximately 99% of all regulated medical devices are cleared by the FDA through the speedy and less than-rigorous 510(k) process, and the FDA reviews 90% of those applications within 90 days.[6] With the emphasis on speed over safety it is not surprising that millions of Americans have been harmed needlessly from defective medical devices such as surgical mesh, metal-on-metal hips, power morcellators, duodenal scopes, birth control devices (Essure), and inaccurate medical device software. It is clear that we need stronger device safety regulations and better postmarket surveillance. When there are problems with medical devices in the real world, patients need to be notified as soon as possible.

Members of our coalition are particularly concerned about the following bills:

**MEDTECH Act (S. 1101)**

The MEDTECH Act deregulates Electronic Health Records (EHRs) and other electronic health technology. This prevents the FDA from collecting adverse event data or recalling defective software, even when the devices have life-threatening flaws. The National Center for Health Research studied FDA-reported recalls of medical software, identifying more than 600 software devices and 1.4 million units recalled for moderate or high risk patient safety issues. They found that if medical software is removed from FDA regulatory oversight, millions of patients would be at risk from defective software. For example, oncology electronic medical record systems were recalled in the past because they calculated and recorded incorrect drug dosages. Clinical decision support systems used during surgery were recalled because they erroneously switched patient data and failed to warn physicians about dangerous drug reactions.

**Advancing Breakthrough Devices for Patients Act (S. 1077)**

This bill would set a low bar for medical devices to qualify for breakthrough status, and encourage shorter or smaller clinical trials, which would make it difficult if not impossible to include subpopulations (women, seniors, racial and ethnic minorities) in the analysis of the trials. The bill would also push FDA to rely on post-market studies rather than ensuring safety or effectiveness before hospitals and patients pay for the devices. A 2015 GAO report found that most required post-market device studies are never completed. In other words, if this bill passes, there would be no conclusive evidence pre-market or postmarket. The

#### **Advancing Hope Act (S. 1878)**

Priority review vouchers allow FDA priority reviews to go to the highest bidder rather than allowing the FDA to prioritize matters of the most public health importance. The bill's priority review vouchers would be applied to drugs that are already in development rather than spurring new drugs because of the long drug development cycle.

#### **The Medical Countermeasure Innovation Act (S. 2055)**

This bill establishes a new priority review voucher program for medical countermeasures (e.g. antidotes to anthrax and other bioweapons). As with existing priority review voucher programs, it does not necessarily reward innovation and prevents FDA from prioritizing matters of greatest public health importance.

#### **The Combination Product Regulatory Fairness Act (S. 1767)**

This bill would broaden the ability of combination products to be classified as devices. This would inappropriately allow products that should be classified as drugs to go through the FDA's less rigorous device clearance/approval process.

#### **Patient Focused Impact Assessment Act (S. 1597)**

The Patient Focused Impact Assessment Act adds a new layer of bureaucracy to the FDA, does not provide safeguards to ensure that patient perspectives will be free of industry influence, and may provide a mechanism for industry to promote drugs directly to consumers for off-label uses.

#### **REGROW Act (S. 2689)**

The REGROW Act is the latest effort to lower research standards and deregulate new treatments. Although this bill was not part of the HELP Committee markups held earlier this year, we understand it might be added to a package bill. The Act allows complex biologic therapies to be conditionally approved without phase III trials and prescribed to patients based on studies in a limited population without proof that the new therapy actually works. If this Act passes, it could lead to the Centers for Medicare and Medicaid (CMS) wasting billions of dollars on medications that were approved by the FDA but do not work.

The Alliance for Regenerative Medicine (ARM) does not support the REGROW Act, because those researchers want "to ensure access to safe and effective

regenerative medicine therapies without putting patients at risk, disadvantaging American therapeutic developers and potentially damaging a very promising field of medicine”(emphasis added).[7] In her recent article about stem cell research in the New England Journal of Medicine, University of Wisconsin law professor and biomedical ethicist R. Alta Charo said, “The best way to find safe effective cures is through the careful steps of clinical trials and treatment monitoring.”[8]

For the remaining Senate FDA-NIH bills, we urge you to only support them if they provide mandatory new funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). If mandatory funding is not included, we strongly urge you to vote against the bills.

### **Funding for NIH & FDA**

Prior to last year’s \$2 billion one-time funding increase, NIH’s funding remained flat for more than a decade (about \$30 billion per year). [9] Unfortunately, the Cures Act \$9 billion increase in NIH research funding is still below what it would have been had Congress not previously allowed NIH’s annual budget to stagnate. [10]

The Cures Act also would provide the FDA with \$550 million in new mandatory funding over five years, but the amount of money pales to the additional workload that the Act assigns to the FDA. New FDA Commissioner, Robert Califf, has warned that Congress needs to provide the FDA with an “adequate and stable source of funding” for the mandates in the legislation.[11]

Adequately funding NIH is essential if we are serious about the Vice President’s Cancer Moonshot, precision medicine, and efforts to find treatments for Alzheimer’s disease, autism, depression, schizophrenia, addiction and other maladies. [12] Underfunding the FDA is likely to slow the approval of new medical products because the agency’s workload has been significantly increased with unfunded mandates.

### **Conclusions**

Members of our coalition agree with most Americans in opposing regulations that would speed the approval of medical products by lowering FDA’s safety and effectiveness standards. We strongly urge you to oppose any bill that weakens FDA’s safety and effectiveness standards, and to ensure that any legislation aimed at improving medical treatments include new mandatory funding for the NIH and the FDA.

AMWA  
Breast Cancer Action  
Center for Medical Consumers  
Connecticut Center for Patient Safety  
MAMA (Mothers Against Medical Error)  
MedShadow Foundation



MISSD

MRSA Survivors Network

National Center for Health Research

National Consumers League

National Organization for Women

National Physicians Alliance

National Women's Health Network

Quinolone Vigilance Foundation

The TMJ Association

Washington Advocates for Patient Safety

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The Patient, Consumer, and Public Health Coalition is an informal coalition of nonprofit organizations representing the interests of millions of patients, consumers, health-care professionals, scientists, and public health experts. The coalition can be reached through Paul Brown at (202) 223-4000 or at [pb@center4research.org](mailto:pb@center4research.org).

1 Nather D, Kaplan S (May 11, 2016). Public wary of faster approvals of new drugs, STAT-Harvard poll finds, STAT.

<https://www.statnews.com/2016/05/11/stat-harvard-poll-drug-approvals/>

2 Burton TM (May 12, 2016). Experts Decry Tying Medical Research Funds to FDA Standards Changes, The Wall Street Journal.

[http://www.wsj.com/articles/experts-decry-tying-medical-research-funds-to-fda-standards-changes-](http://www.wsj.com/articles/experts-decry-tying-medical-research-funds-to-fda-standards-changes-1463045401?utm_campaign=KHN%3A+First+Edition&utm_source=hs_email&utm_medium=email&utm_content=29509000&_hsenc=p2ANqtz-9HTUCoepyRhDPD2qIynH6oQod3KA5hRwrFErW5MLUwakcVVxgoHWW78c7CC07ycSBI5XC4Pu85OP6ZyeJ5jpK1LWPeA&_hsmi=29509000)

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3 Food and Drug Administration (Accessed May 12, 2016). Novel Drugs Summary 2015.

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm474696.htm>

4 Herper M (August 20, 2015). VIEWS: The FDA Is Basically Approving Everything. Here's The Data To Prove It.

<http://www.forbes.com/sites/matthewherper/2015/08/20/the-fda-is-basically-approving-everything-heres-the-data-to-proveit/#23cbf9934938>

5 Baus S, Hassenplug JC (August 9, 2012). Patient Access to Medical Devices—A comparison of U.S. and European Review Processes. New England Journal of Medicine.

<http://www.nejm.org/doi/full/10.1056/NEJMp1204170?rss=searchAndBrowse>

6 Food and Drug Administration (2011). Analysis of Premarket Review Times Under the 510(k) Program.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm263385.htm#a>

- 7 Alliance for Regenerative Medicine (Accessed May 17, 2016). Government Relations and Policy Web site. <http://alliancerm.org/page/government-relations-and-policy> 5
- 8 Char, RA (March 10, 2016). On the Road (to a Cure?)—Stem-Cell Tourism and Lessons for Gene Editing, Perspective, New England Journal of Medicine. <http://www.nejm.org/doi/pdf/10.1056/NEJMp1600891>
- 9 MacGillis A (October 20, 2015). Would Washington's FDA Fix Cure the Patients or the Drug Industry? ProPublica . <https://www.propublica.org/article/would-washingtons-fda-fix-cure-the-patients-or-the-drug-industry>
- 10 National Institutes of Health (Accessed May 13, 2016). National Institutes of Health History of Congressional Appropriations, Fiscal Years 2000-2016. <https://officeofbudget.od.nih.gov/pdfs/FY16/Approp%20History%20by%20IC%20FY%202000%20-%20FY%202016.pdf>
- 11 Mixter B (May 6, 2016). FDA Head Cites Concerns with Cures Bill, Bloomberg BNA. <http://www.bna.com/fda-head-cites-b57982070805/>
- 12 Health and Human Services (Accessed May 13, 2016). President's HHS FY 2017 Budget Factsheet. <http://www.hhs.gov/about/budget/fy2017/budget-factsheet/index.html#>

May 2016 AMWA Signs on to a letter opposing the House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for fiscal year 2017, specifically the language regarding generics labeling.

Dear Representative:

We are writing to urge you to oppose the House Agriculture, Rural Development, Food and Drug Administration, and Related Agencies appropriations bill for fiscal year 2017 because of the inappropriate inclusion of language targeting the Food and Drug Administration (FDA) drug labeling rule. Section 747 of the proposed bill contains a controversial policy rider that would prohibit the FDA from moving forward on a regulatory change that would improve the safety of prescription drugs labeling for consumers by allowing generic drug manufacturers to update safety warnings. The rule, entitled "FDA's Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products (Docket No. FDA-2013-N-0500)," was proposed in November 2013. We strongly support the FDA's labeling proposal. Allowing generic manufacturers to initiate safety updates, as brand-name companies have done for 30 years, is essential to physicians, patients, and their family members, by providing access to better and more accurate information about the risks of medications. Patients and consumers deserve up-to-date information about the prescription drugs they use, including the most up-to-date safety warnings. The FDA's drug labeling rule already has undergone additional scrutiny as a result of policy riders during the FY15 appropriations cycle and the FDA should be able to conclude its work in this important area. We strongly urge your opposition to any appropriations legislation

that includes Section 747, or similar language inhibiting the FDA rule from moving forward.

Thank you for your consideration.

Sincerely,

American Medical Student Association  
American Medical Women's Association  
Annie Appleseed Project Brain Injury  
Association of America Breast Cancer Action Consumers Union  
MRSA Survivors Network  
National Center for Health Research  
National Consumers League  
National Physicians Alliance  
National Women's Health Network  
Prevent Blindness  
Public Citizen  
UP PIRG  
Woodymatters

June 14, 2016 AMWA signs on with the Patient, Consumer, and Public Health Coalition to oppose S. 2912, the Trickett Wendler Right to Try Act of 2016. <https://www.amwa-doc.org/wp-content/uploads/2017/04/Right-to-try-Coalition-letter-2016-FINAL.pdf>

June 14, 2016

The Honorable \_\_\_\_\_

United States Senate

Washington, DC 20510

Dear Senator \_\_\_\_\_,

As members of the Patient, Consumer, and Public Health Coalition, we are writing to express our views as consumers, physicians, scientists, and public health experts regarding S. 2912, the Trickett Wendler Right to Try Act of 2016. We strongly urge you to NOT co-sponsor this bill. This bill is bad for patients, bad for doctors, bad for drug development, and bad for science.

As you may know, the history of the FDA is a history of Congress responding to medical tragedies by requiring FDA to do more to protect patients from harmful medical products. Thalidomide birth defects and deaths and infertility from the Dalkon Shield IUD are just two of many examples. Although the AIDS crisis resulted in a more flexible approach for deadly diseases for which there were no treatments, today's HIV/AIDS advocates are among the FDA's strongest supporters, because the scientific evidence that FDA required of pharmaceutical companies resulted in effective treatments and prevention strategies. The FDA's essential role continues to be to achieve a balance between patients' rights and

societal good. It is critical that, in your role as a Senator, you support the agency in upholding this delicate balance.

The idea behind this bill and other Right to Try laws is to give terminally ill patients access to experimental drugs that have passed phase I testing – testing that is often done on healthy volunteers, not people with serious illnesses. While this type of legislation promises cures, it offers false hope. Since most phase 1 trials include less than 30 patients and are designed only to identify the most immediate side effects, they provide very little information about the drug's safety and effectiveness. In fact, most drugs with promising phase 1 test results are later found to be too risky or ineffective for patients to use. This is especially true for cancer drugs. Under the proposed bill, desperate patients are likely to be exploited by unethical companies that want to sell their unproven treatments at prices that would bankrupt many families. Health insurance companies will not pay for these unproven treatments – if they did, insurance premiums would skyrocket as patients harmed by unproven treatments required more expensive remedial care.

In the recent past, access to experimental bone marrow transplants for breast cancer was expedited due to an early benefit seen in preliminary data. It was not until many women were harmed and some even died that researchers realized a terrible mistake had been made. If doctors and patients can be fooled into trying such a painful and toxic treatment, imagine how often patients would be fooled by treatments that are less painful but ineffective and expensive snake oil.

This legislation would subject patients to a great risk of harm and they would have no legal recourse if things go wrong. In fact, this bill and similar state Right to Try laws reflect the libertarian philosophy of the Goldwater Institute that created them: the patient is on his or her own without any protections or safeguards. The bill explicitly states that drug and device companies as well as physicians cannot be held liable for any tragic outcomes, even if the company or a physician misled the patient. Even worse, if a patient suffers a terrible medical complication from a Right to Try treatment, the insurance company would not need to pay for the medical care that is needed to treat that complication. The only thing worse than a terminal illness is being terminally ill and suffering a major complication as the guinea pig in an experimental treatment that you had to pay for.

There are many other problems with the bill, but perhaps the most important thing for you to know is that the FDA's current compassionate use program already provides patients with the opportunity to try experimental drugs, while offering some protections to patients and society. For example, while physicians and drug companies are required to report the outcomes of experimental treatments obtained through the FDA's compassionate use program, Right to Try laws do not carry such stipulations. Indeed, this bill strips all protections from patients who would use it. Bypassing the oversight of the FDA is not in the best interest of patients or the public health.

The one shortcoming of the FDA's current compassionate use ("expanded access") program is also in the Right to Try bill: the company is not required to provide the experimental drug to the desperate patient. In some cases, that's because the company doesn't have enough doses to provide to patients not in a clinical trial, and in other cases, the company believes that the patient is more likely to be harmed by the product than helped by it. In conclusion, Right to Try laws such as S. 2912 will do more harm than good for patients and society. The bill is opposed by experts in the field as well as by legitimate drug companies. We urge you to oppose the Trickett Wendler Right to Try Act of 2016.

Sincerely,  
American Medical Women's Association  
Connecticut Center for Patient Safety  
DES Action  
Jacobs Institute of Women's Health  
MedShadow Foundation  
National Center for Health Research  
National Physicians Alliance

The Patient, Consumer, and Public Health Coalition can be reached through Tracy Rupp at 202-223-4000 or [tr@center4research.org](mailto:tr@center4research.org).

June 19, 2016 AMWA writes letter to Congressional leaders regarding gun violence prevention

June 19, 2016

The Honorable Paul Ryan  
Pelosi  
Speaker of the House  
U.S. House of Representatives  
Representatives  
Washington, DC 20515  
20515

The Honorable Nancy  
Minority Leader  
U.S. House of  
Washington, DC

The Honorable Mitch McConnell  
Reid  
Majority Leader  
U.S. Senate  
Washington, DC 20510

The Honorable Harry  
Minority Leader  
U.S. Senate  
Washington, DC 20510

Dear Congressional Leaders:

On behalf of the American Medical Women's Association, I am writing to urge Congress to enact legislation to reduce the incidence of gun violence and related deaths in the United States. Following the recent events in Orlando, as well as the daily gun violence that plagues American cities and towns, we believe that gun violence has now become a public health crisis in American. A bipartisan consensus is emerging in Congress to ensure the safety of Americans and reduce the threat of injury or death from firearms.

Deaths and injuries from firearms are not just a result of mass shootings, they are an everyday occurrence in our communities, homes, schools, and workplaces. Nearly 35,000 Americans die at the hand of a gun each year, costing billions of healthcare dollars and countless lost years of life. Physicians agree that decreasing the threat of gun violence will include: reversing the Dickey Amendment to allow language that provides funding for CDC research on gun violence, requiring criminal background checks for all firearm purchases, limiting the availability of assault-style weapons and large capacity magazines, allowing physicians to discuss gun safety within the confines of the doctor-patient relationship, and disallowing weapons from institutions of higher education.

The American Medical Women's Association is the largest specialty organization representing women physicians. AMWA believes that the threat to American public health is too great for Congress to delay the adoption of the above measures to reduce the threat of gun violence and allow for the study of the problem. We ask that Congress make reasonable and evidence-based decisions about guns that will ensure the safety of our patients and all citizens.

Sincerely,

Kim Templeton, MD  
President, American Medical Women's Association

June 21, 2016 AMWA letter in support of New York Bill for the identification and treatment of trafficking victims by health care professionals.

**MEMORANDUM IN SUPPORT**

New York A.8650-B/S.6835-B

**The Identification and Treatment of Trafficking Victims by Health Care Professionals**

**Date:** June 21, 2016

**Subject:** We, the undersigned professional medical organizations, urge supporting [New York A.8650-B/S.6835-B](#), *"The Identification and Treatment of Trafficking Victims by Health Care Professionals."* This legislation requires every general hospital, public health center, diagnostic center, treatment center or outpatient department to provide identification, assessment, and appropriate treatment or referral of persons suspected as human trafficking victims and requires notification, when required, to social services when the person is under the age of 18.

Human trafficking is a major public health problem, both at home here in the United States and around the globe. It constitutes an egregious human rights violation, whereby victims experience a range of traumas and abuses that can cause a number of acute and chronic physical and mental health problems. Victims of trafficking typically sustain multiple types of injuries; sexual and physical assault; develop a range of gynecologic problems such as unintended pregnancies and abortions, and often suffer a number of long term chronic health problems that go unattended. Mental health issues often include post-traumatic

stress disorder, major depression and suicidal ideation, as well as general anxiety disorder. A range of healthcare professionals are known to take care of trafficking victims in a number of different healthcare settings, including emergency rooms, primary care clinics and dental clinics. Research has shown that 28-88% of trafficking victims had seen a healthcare professional at some point during the time they were under a trafficker's control.<sup>2</sup> This means that physicians, nurses and other health care providers can play a substantial role in identifying and treating affected individuals, as well as connecting them with important community resources. But this can only occur if healthcare professionals are adequately trained to do so. Currently, training on identifying and caring for victims of trafficking is not routinely taught in either health care professional schools or in residency programs. Thus, most practicing physicians have never been exposed to training on human trafficking.

This legislation will go a long way in helping to remediate this problem, as it requires that healthcare professionals and others within medical institutions/facilities are appropriately trained to identify and intervene on behalf of trafficking victims. New York State can be a leader in creating a model law on how to help educate health professionals to address this major public health issue. **We, the undersigned organizations, strongly urge the Governor of the State of New York to sign A.8650-B/S.6835-B into law.**

#### **American Medical Women's Association**

July 18, 2016 AMWA joined the Patient, Consumer, and Public Health Coalition to provide comments on the draft guidance regarding Use of Electronic Health Record Data in Clinical Investigations. <https://www.amwa-doc.org/wp-content/uploads/2017/04/July-18-EHRs-Comments.pdf>

July 18, 2016  
Food and Drug Administration  
Division of Dockets Management (HFA-305)  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Comments of members of the Patient, Consumer, and Public Health Coalition on the draft guidance Use of Electronic Health Record Data in Clinical Investigations [Docket No. FDA-2016-D-1224]

Members of the Patient, Consumer, and Public Health Coalition appreciate the opportunity to comment on the draft guidance "Use of Electronic Health Record Data in Clinical Investigations."

A major goal of the draft guidance is to "facilitate the use of EHR data in clinical investigations."<sup>1</sup> Although EHRs are not under the direct control of the FDA (the

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<sup>2</sup> Baldwin S, Eisenman D, Sayles J, Ryan G, Chuang K. Identification of human trafficking victims in health care settings. *Health and Human Rights*. 2011;13(1):36-49.; Family Violence Prevention Fund. Turning Pain into Power: Trafficking Survivors' Perspectives on Early Intervention Strategies. San Francisco, CA: 2005.; and Lederer L, Wetzel C. The Health Consequences of Sex Trafficking and Their Implications for Identifying Victims in Healthcare Facilities. *Ann Health Law*. 2014;23(1):61-91.

systems belong to healthcare organizations and institutions that use them), the Agency does need to develop a clear process for *accepting* EHR data for use in clinical investigations. The draft guidance is a step in the right direction but needs to better address key issues.

The draft guidance addresses how the FDA will ensure the EHR data's validity, reliability, and integrity, and how the agency will verify the integrity of the EHR data during on-site inspections and audits of the organizations that control the data.

### **On-site inspections**

We agree with the draft guidance that clinical investigators must retain all paper and electronic source documents for as long as required by regulations, and EHR data must meet FDA's inspection, recordkeeping and record retention requirements. And, importantly, study monitors must have "suitable access to all relevant subject information pertaining to a clinical investigation."<sup>1 2</sup>

However, we are concerned that the draft guidance does not mention how often FDA will do on-site inspections. If FDA does not establish a schedule of on-site inspections, they may never be done and this could lead to poor quality data.

### **Quality and integrity**

The draft guidance states that "when EHRs are used as a source of data in clinical investigations, sponsors should ensure that the data are 'attributable, legible, contemporaneous, original and accurate (ALCOA).'" If the data does not meet all five of these attributes, will the data be rejected by the FDA?

An inherent problem with using EHRs for clinical investigations is that EHRs are currently designed to assist in delivering health care — not to generate medical evidence. A July 2016 Article in *JAMA Internal Medicine* notes that "practices like blinding, randomization, or standardized-event recording are more difficult to implement in systems that are oriented toward care. Health care systems represent inefficient environments to which to learn about differential effects of novel drugs."<sup>2</sup> The draft guidance notes that the use of EHRs for clinical investigations may require additional "considerations, planning, and management" but it does not go into detail on how to accomplish this.

The draft guidance recommends, but does not require, the use of certified EHR technology. The U.S. Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) has a voluntary certification program for health IT. EHR technology certified by ONC'S Program meets privacy and security protection requirements.

The draft guidance allows EHRs not certified by ONC to be used for clinical investigations as long as they include adequate controls such as limiting access to the electronic systems, identifying the authors of records, providing audit trails, ensuring records are retained for FDA inspections, and assuring patient privacy rights. Although the adequate controls address key issues, there would be more consistency in investigations, if all EHRs for clinical investigations were required to use certified



EHR technology.

In using EHRs for clinical investigations, the draft guidance recommends that extracted data is checked for consistency and completeness. It also recommends that corrections be made when errors are found “to properly align the source data with the extracted data.” We are concerned that unless FDA spot checks the data, errors will not be corrected.

The draft guidance notes that software updates could “affect the reliability and integrity of EHR data entering the sponsor’s electronic system.” This is a major concern. A recent review of FDA data by the National Center for Health Research found that over the last 5 years, more than 600 different software devices totaling over 1.4 million units were recalled for moderate or high risk patient safety issues. For example, oncology electronic medical record systems were recalled because they erroneously switched patient data and failed to warn physicians about dangerous drug reactions.

### **Interoperability & audit trails**

The draft guidance encourages the use of interoperable systems in order to “reduce errors in data transcription and provide data that is more accurate.” We agree that interoperability will reduce transcription errors but if the data was incorrect to begin with, it will not provide more accurate data.

The draft guidance states that adequate methods of audit trails are needed to monitor, track and document all changes made to information in the EHR regarding the clinical investigation. However, the draft guidance fails to define the phrase “adequate methods.”

One of the major risks associated with EHRs are data breaches. Data breaches could negatively affect a subject’s employment or ability to get insurance. The draft guidance states, “Sponsors should consider whether there are any reasonably foreseeable risks with the use of EHRs...that must be described to the subject in the informed consent.” We recommend that the risk of data breaches be communicated to subjects at least twice—once in writing and once again verbally.

### **Conclusions**

EHRs can provide investigators “access to real-time and longitudinal health care data”<sup>1</sup> and can provide post-trial follow-up information on safety and efficacy of medical products. However, we think this draft guidance still needs work. It does not address how inaccuracies in the data will be corrected, how often FDA will do on-site inspections, and ways to mitigate the risks of data breaches.

American Medical Women’s Association  
MRSA Survivors Network  
National Center for Health Research  
Our Bodies Ourselves  
Quinolone Vigilance Foundation

Washington Advocates for Patient Safety

*The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or [pb@center4research.org](mailto:pb@center4research.org)*

1 Food and Drug Administration (May 2016). Use of Electronic Health Record Data in Clinical Investigations (Draft Guidance).

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm501068.pdf>

2 London AJ, Kimmelman J (July 2016). Accelerated Drug Approval and Health Inequality. *JAMA Internal Medicine*, Volume 176, Number 7.

<http://archinte.jamanetwork.com/article.aspx?articleid=2527394>

June 20, 2016 AMWA signs on with more than 175 organizations to urge Senate To support the Murphy amendment which provides for expanded background checks on gun sales.

<http://www.bradycampaign.org/sites/default/files/Final%20Murphy%20Amendment%20Support%20and%20Grassley%20oppose%20letter%20SIGN%20ON.pdf>

July 25, 2016 AMWA joins the Patient, Consumer, and Public Health Coalition to support the FDA's proposed rule to ban electrical stimulation devices (ESDs) used to treat self-injurious behavior (SIB) or aggressive behavior (AB). <https://www.amwa-doc.org/wp-content/uploads/2017/04/July-25-Comments-ESDs-July-21.pdf>

July 25, 2016

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852.

**Comments of members of the Patient, Consumer, and Public Health Coalition on Proposed Rule To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior  
[Docket No. FDA-2016-N-1111]**

Members of the Patient, Consumer, and Public Health Coalition strongly support the FDA's proposed rule to ban electrical stimulation devices (ESDs)\* used to treat self-injurious behavior (SIB) or aggressive behavior (AB). ESD treatments are ineffective and have serious side effects, and there are alternative, less stressful treatments available.

The goal of ESDs is to reduce self-injurious or aggressive behavior by punishing it with shocks. However, the strategy of preventing violent behavior in any situation by using a painful punishment is rejected by most experts. That is why the overwhelming majority of SIB and AB patients are not treated with ESDs. Only one facility in the U.S. manufactures and uses ESDs, the Judge Rotenberg Educational Center, Inc. (JRC). Even if ESDs were a safe, effective, and humane

treatment, those used by JRC as recently as 2012 had not been cleared by the FDA. FDA has sent warning letters to the Center at least three times stating that the devices are in violation of FDA regulations because they have been modified to increase the voltage they provide but a new application has not been filed with the FDA.<sup>1, 2</sup>

Because of advances in human rights and behavioral therapy, nearly half of the States prohibit the use of ESDs.<sup>3</sup> The United Nations has said use of ESDs, such as those used by the Rotenberg Center, constitutes a violation of the UN Convention Against Torture, and would not be legal if used even against convicted terrorists.<sup>4, 5</sup>

### **Risks**

ESDs have a long list of harms including “depression, PTSD, anxiety, fear, substitution of other negative behaviors, worsening of underlying symptoms, and learned helplessness, as well as the physical risks of pain, and skin burns.”<sup>3</sup> The devices are associated with an increased risk of “suicidality, chronic stress, neuropathy, and injuries from falling.”<sup>3</sup> They are associated with “nightmares, flashbacks of panic and rage, hypervigilance, insensitivity to fatigue or pain, changes in sleep patterns, loss of interest, difficulty concentrating, and withdrawal from usual activity.”<sup>3</sup>

We agree with the FDA that adverse events are likely to be under-reported because the children and adults subjected to ESD often have problems that make it difficult to persuasively communicate to anyone who would be likely to report adverse events to the FDA. In addition, the individuals administering ESDs are unlikely to be taught or encouraged by their employer (who requires them to administer ESDs) to report adverse events resulting from ESD “treatment.”

### **Benefits**

Although the scientific literature reports that ESD shocks can immediately interrupt SIB or AB, these studies have been criticized for “weak study design, failure to control for concomitant treatments, small size, lack of peer review, and conflicts of interest.”<sup>3</sup> We agree with the FDA that “the evidence is inadequate to establish that ESDs improve individuals' underlying conditions or...reduce or cease the target behavior to achieve durable long-term reduction of the target behavior.” The established risks are even more unacceptable given the lack of evidence of benefits.

### **Alternative treatments**

There is clear research evidence that positive reinforcement is more effective and longer-lasting than negative reinforcement (punishment). We agree with the FDA that positive-based behavioral approaches are effective at reducing self-injurious and aggressive behavior, providing greater benefits and less risk than ESDs. We also agree with the FDA that “addressing the underlying causes of SIB and AB...rather than suppressing behaviors with shocks not only avoids the risks

posed by ESDs, but can achieve durable, long-term benefits.”

### **Conclusions**

ESDs are not established to be effective for most self-injurious or aggressive behaviors and represent a substantial and unreasonable risk of injury. They are also inhumane. For the above reasons, we strongly support the ban on electrical stimulation devices.

American Medical Women’s Association  
MAME  
MRSA Survivors Network  
National Center for Health Research  
National Physicians Alliance  
Washington Advocates for Patient Safety  
WoodyMatters

*The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or [pb@center4research.org](mailto:pb@center4research.org).*

1 Willingham E (April 22, 2016). FDA Proposes Ban On Electric Shock Devices Used On Autistic Children. *Forbes*.

<http://www.forbes.com/sites/emilywillingham/2016/04/22/fda-seeks-to-ban-electric-shock-devices/#7e7c39e87ead>

2 Food and Drug Administration (December 6, 2012). Inspections, Compliance, Enforcement, and Criminal Investigations: Warning Letter CMS#367480, the Judge Rotenberg Educational Center.

<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2012/ucm331291.htm>

3 Federal Register (April 25, 2016). Food and Drug Administration: Banned Devices; Proposal To Ban Electrical Stimulation Devices Used To Treat Self-Injurious or Aggressive Behavior; Proposed Rule. [Docket No. FDA-2016-N-1111] <https://www.federalregister.gov/articles/2016/04/25/2016-09433/banned-devices-proposal-to-ban-electrical-stimulation-devices-used-to-treat-self-injurious-or>

4 Ahem, L (October 2, 2010). Disabled children at Mass. School are tortured, not treated. *The Washington Post*. <http://www.washingtonpost.com/wp-dyn/content/article/2010/09/17/AR2010091705376.html>

5 Burkholder A (August 5, 2014). Controversy over shocking people with autism, behavioral disorders. *CBS News*.

<http://www.cbsnews.com/news/controversy-over-shocking-people-with-autism-behavioral-disorders>

*\*We are aware that ESDs are not used in electroconvulsive therapy (ECT or electroshock therapy) and that this proposed rule does not apply to ECT devices.*

August 2, 2016 AMWA joins the Patient, Consumer, and Public Health Coalition in supporting the FDA's draft guidance on Labeling for Biosimilar Products; Draft Guidance [FDA-2016-D-0643]. <https://www.amwa-doc.org/wp-content/uploads/2017/04/August-2-Labeling-for-Biosimilar-Products.pdf>

August 2, 2016  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Comments of members of the Patient, Consumer, and Public Health Coalition on Labeling for Biosimilar Products; Draft Guidance [FDA-2016-D-0643]

Members of the Patient, Consumer, and Public Health Coalition support the Food and Drug Administration's (FDA) draft guidance on "Labeling for Biosimilar Products." The draft guidance will protect patients and consumers by requiring biosimilar companies to update their labels when safety issues arise.

### **Background**

The Biologics Price Competition and Innovation Act of 2009, signed into law as part of the Affordable Care Act, created an abbreviated pathway to license biosimilar products. 1 A product is a biosimilar if it has no clinically meaningful differences compared to the reference product in terms of "safety, purity, and potency." 1 Because there is no meaningful difference, we agree with the FDA that biosimilars labeling should include a description of the clinical data that supported safety and efficacy of the reference product. We agree with FDA that the biosimilar prescribing information (package insert) relies mainly on the safety and effectiveness information from the labeling for the reference product.2

### **Specific Recommendations on Content of Biosimilar Product Labeling**

FDA also notes that biosimilar products' labels may differ from the reference product labeling (have "appropriate product-specific modifications") in order to conform to the Physician Labeling Rule (PLR) and the Pregnancy and Lactation Labeling Rule (PLLR), and other safety issues. We agree since this will add to the safer use of biosimilars. Also, according to a recent survey of European physicians, they "prefer more product-specific information in the biosimilar label."3

### **Revising Biosimilar Product Labeling**

We strongly agree with the FDA that "all holders of marketing applications for biological products have an ongoing obligation to ensure their labeling is accurate and up to date" (emphasis added).1 We see no reason why this should not include PLR and PLLR information for the reference product. To ensure that the product is used safely, both the reference product and the biosimilar product application holders must be able to update their labeling.

## **Conclusions**

We strongly support the “Labeling for Biosimilar Products” draft guidance. It will protect patients and consumers by ensuring the important labeling safety information is updated for both biosimilars and the reference products.

American Medical Student Association  
American Medical Women’s Association  
Center for Medical Consumers  
Connecticut Center for Patient Safety  
MAME  
MRSA Survivors Network  
National Center for Health Research  
National Physicians Alliance  
National Women’s Health Network  
Quinolone Vigilance Foundation  
Washington Advocates for Patient Safety  
WoodyMatters

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or at [pb@center4research.org](mailto:pb@center4research.org)

1 Federal Register (April 4, 2016). Food and Drug Administration draft guidance “Labeling for Biosimilar Products.”

2 Food and Drug Administration (April 1, 2016). News & Events Form our perspective: Biosimilar product labeling.  
[http://www.fda.gov/Drugs/NewsEvents/ucm493240.htm?source=govdelivery&utm\\_medium=email&utm\\_source=govdelivery](http://www.fda.gov/Drugs/NewsEvents/ucm493240.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery) 2/3

3 Hallersten A, Fürst W, Mezzasalma R (June 2016). Physicians prefer greater detail in the biosimilar label (SmPC) - Results of a survey across seven European countries. Regul Toxicol Pharmacol.  
<http://www.ncbi.nlm.nih.gov/pubmed/27041395>

August 9, 2016 AMWA joins the Patient, Consumer, and Public Health Coalition in providing comments on the draft guidance regarding the Dissemination of Patient-Specific Information from Devices by Device Manufacturers. [Docket No. FDA-2016-D-1264]. <https://www.amwa-doc.org/wp-content/uploads/2017/04/Device-Info-Comments.pdf>

August 9, 2016  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
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Rockville, MD 20852.

**Comments of members of the Patient, Consumer, and Public Health Coalition on the draft guidance Dissemination of Patient-Specific**

## **Information from Devices by Device Manufacturers [Docket No. FDA-2016-D-1264]**

Members of the Patient, Consumer, and Public Health Coalition appreciate the opportunity to comment on the draft guidance Dissemination of Patient-Specific Information from Devices by Device Manufacturers. We generally support the draft guidance but the document needs further clarification, especially the paragraph on the Health Insurance Portability and Accountability Act (HIPAA).

The purpose of the draft guidance is to “clarify that manufacturers may share with a patient patient-specific information” collected from devices regarding that same patient. In other words, device companies may share with a patient the information that the device collects about him or her. The draft guidance defines “patient-specific information” as including “recorded patient data, device usages/output statistics, healthcare provider inputs, incidence of alarms, and/or records of device malfunctions or failures.”<sup>1</sup> We agree with FDA that providing the above information “will empower patients to be more engaged with their healthcare providers in making sound medical decisions.”<sup>1 2</sup>

### **Content**

FDA recommends that device makers take steps to avoid “disclosure of confusing or unclear information that could be misinterpreted” by patients. The draft guidance does not provide details on how device makers should accomplish this goal. If the information from the device is summarized, key data could be omitted. Alternatively, if all data is released (e.g. via data dump), the information could be overwhelming and useless to the patient.

Information communicated to patients should be done in a manner that is easy for them to understand. Only 12 percent of adults have proficient health literacy, according to the National Assessment of Adult Literacy. <sup>2</sup> This indicates that many patients may not be able to understand information that is complicated or communicated using medical terminology. Patients benefit from interactive, simple to follow, and practical communications that are appropriate to the intellectual and social skills of the patient and the caregiver.<sup>3</sup>

FDA notes that device makers “may share patient-specific information...with patients at the patient’s request without obtaining additional premarket review before doing so.” FDA then cautions that additional information from devices shared with patients by the manufacturer could meet the definition of labeling and would be subject to FDA labeling regulations. Although FDA cites the labeling section of the Federal Food, Drug, and Cosmetic Act (section 201 (m)), the draft guidance does not provide an example of when information shared from a device would meet the labeling definition.

FDA states that often the patient-specific information is “accessible by the patient’s healthcare providers,” or patients may contact the manufacturer directly

to obtain the information. The advantage of receiving the information from a healthcare provider is that the information will more likely be interpreted and put in context, and the patient can ask follow-up questions. The disadvantage is that the patient will have to pay for the appointment, and may not be able to access the information in a timely manner.

We agree with FDA that patient-specific information shared with patients should be “comprehensive and contemporary” and the information from a patient’s blood pressure device provides a good example. But again, we are concerned that “comprehensive” could become a useless “data dump.”

### **Context**

We agree with FDA that patient-specific information should include “relevant context” so that the information will not be misinterpreted, “thus leading to incorrect or invalid conclusions.” Invalid conclusions could lead to additional tests (i.e. over diagnosis), or false negatives, which could put the patient’s health at risk. We also agree with FDA that device makers who provide patient-specific information should include information “about whom to contact for follow-up information.”

### **HIPAA**

The draft guidance dedicates one paragraph to HIPAA. It notes that HIPAA protections apply to device makers to prevent the sharing of “individually identifiable health information” but the 3 protections “are not intended to prevent a device manufacturer from sharing patient-specific information with the affected patient.”

A recent article criticized FDA’s definition of “Patient-specific information” because it “appears to be, at least in part, inconsistent with HIPAA’s definition” of Protected Health Information (PHI). The article also notes that “there are a number of instances where a device manufacturer may be a HIPAA-regulated entity.”<sup>4</sup> For example, if a medical device company has contracted with a covered entity (such as a doctor’s office or hospital) so that the device will transmit electronic protected health information directly to the provider, compliance with HIPAA requirements is mandated.<sup>5</sup> This type of scenario is not addressed in the draft guidance.

Others have noted that the guidance appears to offer an incorrect interpretation of HIPAA when it states that device manufacturers are prevented under HIPAA from sharing this information with covered entities, such as health plans and health-care providers that electronically transmit health data, without the patient’s consent.<sup>6</sup> We agree that HIPAA was never meant to prohibit patient data collected by devices from being shared with the patients’ own physicians. Clarification of these issues is needed.



Also, nothing is mentioned about encrypting sensitive personal health information, or the risk of data breaches. The draft guidance should recommend steps device makers can take to mitigate the risk of data breaches, and to make sure the information is not compiled in any databases that are shared with health plans or healthcare providers.

## **Conclusions**

We generally support this brief draft guidance but the HIPAA section needs clarity, and Content section needs more details on how device makers can avoid disseminating “confusing or unclear information” to patients.

American Medical Women's Association  
Breast Cancer Action  
Connecticut Center for Patient Safety  
MRSA Survivors Network  
National Center for Health Research  
National Consumers League  
Our Bodies Ourselves  
The TMJ Association  
Washington Advocates for Patient Safety

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at (202) 223-4000 or [pb@center4research.org](mailto:pb@center4research.org)

1 Food and Drug Administration (June 10, 2016). Dissemination of Patient-Specific Information from Devices by Device Manufacturers; Draft Guidance of Industry and Food and Drug Administration Staff.  
<http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm505756.pdf>

2 Quick Guide to Health Literacy. US Department of Health and Human Services.  
<https://health.gov/communication/literacy/quickguide/factsbasic.htm>

3 Schooley B, San Nicolas-Rocca T, Burkhard R. Patient-provider communications in outpatient clinic settings: a clinic-based evaluation of mobile device and multimedia mediated communications for patient education. JMIR Mhealth Uhealth. 2015 Jan 12;3(1):e2.  
<http://www.ncbi.nlm.nih.gov/pubmed/25583145>

4 Weinrieb JM, Weeda JM (June 15, 2016). FDA Publishes Draft Guidance on Dissemination of Patient-Specific Data—But Doesn’t Say Much About HIPAA. OFW Law. <http://www.ofwlaw.com/2016/06/15/fda-publishes-draftguidance-dissemination-patient-specific-data-doesnt-say-much-hipaa/>

5 Hartford, J (August 25, 2015). Are your medical devices HIPAA compliant? MDDI DeviceTalk. <http://www.mddionline.com/blog/devicetalk/are-your-medical-devices-hipaa-compliant-08-25-15>.

6 Williamson MD (June 13, 2016). FDA Guidance on Device Data Sharing Aligns With HIPAA: Attorney. Bloomberg BNA. <http://www.bna.com/fda-guidance-device-n57982074036/>

August 2016 AMWA signs letter to CMS regarding concern that lower reimbursement rates on DEXA scans might impact access to screening and follow up DEXA scans.

August 25, 2016 AMWA signs letter to California Governor Jerry Brown to support AB 1762 (Campos) Vacating Convictions for Human Trafficking victims as amended.

August 25, 2016

Governor Jerry Brown  
c/o State Capitol, Suite 1173  
Sacramento, CA 95814

**RE: AB 1762 (CAMPOS) –SUPPORT AS AMENDED**

Dear Governor Brown,

The American Medical Women's Association (AMWA) is writing to ask for your support for AB 1762 (Campos) Vacating Convictions for Human Trafficking victims. We support this bill as amended.

The American Medical Women's Association (AMWA) is an organization that functions at the local, national, and international level to advance women in medicine and improve women's health. Founded in 1915, AMWA is the oldest multi-specialty organization of women in medicine. AMWA's programs help provide leadership, advocacy, education, mentoring and strategic alliances. As the vision and voice of women in medicine for nearly a century, AMWA empowers women to lead in improving health for all, within a model that reflects the unique perspective of women.

Human trafficking victims are often forced to commit crimes by their traffickers as part of their trafficking experience. Due to their traffickers' explicit threats, the trauma bond with their traffickers, or their own lack of self-identification as a crime victim, trafficking victims in California will often be convicted multiple times for crimes their traffickers forced them to commit. This is most evident for sex trafficking victims for crimes related to prostitution, but both sex and labor trafficking victims are also forced to commit a wide range of other crimes such as drug use, sale or cultivation, theft, truancy, public indecency or fraud related crimes.

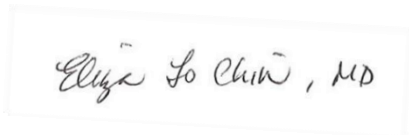
Trafficking victims who finally escape from their traffickers and seek to rebuild their lives then experience the substantial barriers that criminal convictions create on their pathway to recovery. These hurdles include barriers to employment, housing, public benefits, and other supportive systems.

AB 1762 puts in place important protections for trafficking survivors forced to commit crimes by their traffickers. It allows:

- human trafficking victims to vacate convictions for all non-violent crimes they committed as a direct result of human trafficking. It adjusts the standard of proof required under current law and creates presumptions for proving the trafficking experience so that trafficking victims are not re-traumatized by the process of clearing their criminal records.
- Fully clears criminal records, as it extends to trafficking victims the same standards of sealing arrest and court records that are currently provided for factually innocent persons wrongly convicted of crimes.
- Explicitly permits human trafficking victims to state that they have never been arrested for, charged with or convicted of the crime in question and it prohibits the denial of rights or benefits, including employment and housing benefits, based on the arrest, charge or conviction.
- Provides additional protections to minors by establishing a conclusive presumption that sex crime convictions for acts committed when the victim was under 18 years old were the direct result of human trafficking, requiring the resulting conviction to be vacated.

AMWA urges you to support AB 1762, as amended, to help human trafficking victims face fewer barriers to recovery from their trafficking experience.

Sincerely,

A handwritten signature in cursive script that reads "Eliza Lo Chin, MD". The signature is written in dark ink on a light-colored background.

Eliza Lo Chin, MD, MPH  
Executive Director  
American Medical Women's Association

August 25, 2016 AMWA writes letter to California Governor Brown and Senators to support AB 1761 Affirmative Defense for Human Trafficking Victims as amended.

August 25, 2016

Governor Jerry Brown  
c/o State Capitol, Suite 1173  
Sacramento, CA 95814

**RE: AB 1761 (Weber) –SUPPORT AS AMENDED**

Dear Governor Brown,

The American Medical Women's Association (AMWA) is writing to urge your support for AB 1761 (Weber) Affirmative Defense for Human Trafficking victims. Human trafficking victims are some of the most vulnerable people in our community. They are essentially modern day slaves. Despite the widespread recognition that they are victims, the law continues to treat human trafficking victims as criminals with respect to the crimes their traffickers force them to commit. Therefore, we support this bill as amended.

The American Medical Women's Association (AMWA) is an organization that functions at the local, national, and international level to advance women in medicine and improve women's health. Founded in 1915, AMWA is the oldest multi-specialty organization of women in medicine. AMWA's programs help provide leadership, advocacy, education, mentoring and strategic alliances. As the vision and voice of women in medicine for nearly a century, AMWA empowers women to lead in improving health for all, within a model that reflects the unique perspective of women.

Human Trafficking is a unique crime in that traffickers often benefit from having their victims commit illegal acts and may force both children and adults to commit a diverse range of crimes. Traffickers also reinforce their power and control over victims by instilling fear of law enforcement and the systems designed to protect them so that victims-both adults and children- often initially lie to law enforcement about the circumstances of their trafficking experience or proactively attempt to protect their traffickers.

Because of the unique nature of the trafficking crime, California must take proactive steps to protect these victims and create multiple pathways for them to be identified as the victims they are so that the real perpetrators can be prosecuted. California must also enact measures to ensure that the complexities of trafficking crimes can be appropriately described to judges and juries.

AB 1761 puts in place an important additional protection for victims to ensure they are not convicted of crimes their traffickers force them to commit by creating an affirmative defense for trafficking victims. It also strengthens the ability of the judicial system to more fully describe the complexity of this crime through expert testimony.

AMWA urges you to support AB 1761, as amended, and help better protect human trafficking victims in our state.

Sincerely,

A handwritten signature in cursive script that reads "Eliza Lo Chin, MD". The signature is written in dark ink on a light-colored background.

Eliza Lo Chin, MD, MPH

Executive Director  
American Medical Women's Association

September 19, 2016 AMWA joins the Patient, Consumer, and Public Health Coalition in supporting the The Food Additive Petition to amend or revoke food additive regulations regarding food processing and packaging involving specific phthalates filed by Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; [Docket No. FDA-2016-F-1253]. <https://www.amwa-doc.org/wp-content/uploads/2017/04/Food-Additive-Petition-Comments.pdf>

September 19, 2016  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Comments of members of the Patient, Consumer, and Public Health Coalition on The Food Additive Petition Filed by Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; [Docket No. FDA-2016-F-1253]**

Members of the Patient, Consumer, and Public Health Coalition strongly support the food additive petition to amend or revoke food additive regulations regarding food processing and packaging involving specific phthalates.<sup>1</sup> We strongly urge the FDA to ban the use of these ortho-phthalates for use in the production, storage, and packaging of food.

More commonly known as phthalates, ortho-phthalate metabolites are detectable in nearly everyone in the U.S., <sup>2</sup> primarily because of the food we eat. <sup>3</sup> While exposures to specific phthalates may be low for many individual foods, they are present in a wide variety of foods and so the cumulative level is much higher. <sup>4</sup>, <sup>5</sup>, <sup>6</sup>

Phthalate exposure can have diverse and long-lasting harms. Phthalates such as DEHP are probable human carcinogens.<sup>7</sup> Exposure before birth and during early life has been linked to numerous problems with brain development. These include Attention Deficit Hyperactivity Disorder (ADHD) related behaviors, impaired social behavior, aggression, depression, and lower IQ. <sup>8</sup> Increased exposure causes reproductive problems for both sexes, including abnormal testicle development and preterm birth. <sup>9</sup>

Eleven phthalates have been found to affect reproductive, developmental and endocrine health, and the remaining substances do not have sufficient evidence to judge their safety. As such, it is impossible to conclude that there is “reasonable certainty of no harm.” We agree with the petitioners that phthalates should be addressed as a class because if phthalates are considered on an individual basis, one harmful phthalate will likely replace another harmful one. Phthalates contaminate food at different stages of production and storage.<sup>10</sup> We support the extensive scope of the petition to cover all of the steps in processing and packaging of food.

We note that government agencies have already banned or limited the use of certain phthalates covered by this food additive petition. The Consumer Product Safety Commission has banned the use of six of these phthalates from children’s toys and other products due to these health concerns for this vulnerable population.<sup>11</sup> The FDA already limits/warns about the use of DEHP in medical devices<sup>12</sup> and DEHP and DBP in drugs.<sup>13</sup> Clearly, the same chemicals in our food is potentially even a greater risk.

### **Conclusions**

Our Coalition and member groups have commented or testified to the FDA on phthalates and food contact issues for several years. In 2010, members of our coalition submitted comments in support of the FDA’s proposed rule regarding allowable DEHP levels in bottled water (see Docket NO. FDA-1993-N-0259).

The National Center for Health Research’s Dr. Anna Mazzucco spoke at the December 9, 2014 FDA meeting on expanding the Redbook to enhance the safety of food and products. Dr. Mazzucco noted that “Current evaluation of food additives for carcinogenic activity is narrowly focused on genotoxic mechanisms of action. She added that the FDA should add tests for endocrine disruption to its toxicological evaluation of food contact substances and additives to ensure that all food contact substances, both old and new, are safe.”

In summary, we agree with the March 18, 2016 letter from the Natural Resources Defense Council and other groups to the Center for Food Safety and Applied Nutrition. The letter states that “there is no longer a reasonable certainty of no harm for the food contact use of the 30 phthalates.” We echo their concerns that exposure levels to U.S. citizens of these phthalates are above the tolerance for the class of chemicals. The FDA should ban the use of phthalates for use in the production and storage of food.

American Medical Student Association  
American Medical Women's Association  
Breast Cancer Action  
Breast Cancer Consortium  
Mothers Against Medical Error  
MRSA Survivors Network

National Center for Health Research  
National Consumers League  
National Organization for Women  
Our Bodies Ourselves  
Washington Advocates for Patient Safety

The Patient, Consumer, and Public Health Coalition can be reached through Paul Brown at pb@center4research.org or at (202) 223-4000.

- 1 Federal Register (May 20, 2016). Food and Drug Administration, notice of petition. Breast Cancer Fund, Center for Environmental Health, Center for Food Safety, Center for Science in the Public Interest, Clean Water Action, Consumer Federation of America, Earthjustice, Environmental Defense Fund, Improving Kids' Environment, Learning Disabilities Association of America, and Natural Resources Defense Council; Filing of Food Additive Petition.
- 2 National Health and Nutrition Examination Survey (NHANES) (October 2014). Phthalates and plasticizers metabolites- Urine (PHTHTE\_G); years of content 2011-2012. [http://wwwn.cdc.gov/Nchs/Nhanes/2011-2012/PHTHTE\\_G.htm](http://wwwn.cdc.gov/Nchs/Nhanes/2011-2012/PHTHTE_G.htm)
- 3 Consumer Product Safety Commission (July 2014). Chronic Hazard Advisory Panel On Phthalates and Phthalate Alternatives. <https://www.cpsc.gov/PageFiles/169876/CHAP-REPORT-FINAL.pdf>
- 4 Sathyanarayana S et al (2013). Unexpected results in a randomized dietary trial to reduce phthalate and bisphenol A exposures. *J Expo Sci Environ Epidemiol*. 23(4):378-384.
- 5 Schechter A et al (2013). Phthalate concentrations and dietary exposure from food purchased in New York State. *Environ Health Perspect*. 121(4):473-479. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3620091/>
- 6 Serrano SE, Braun J, Transande L, Dills R, Sathyanarayana S (2014). Phthalates and diet: a review of the food monitoring and epidemiology data. *Environ Health* 13:43.
- 4 Agency for Toxic Substances and Disease Registry (2002). Toxicological profile for di (2-ethylhexyl) phthalate. Update. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.
- 8 Ejaredar M, Nyanza EC, Ten Eycke K, Dewey D (2015). Phthalate exposure and children's neurodevelopment: A systematic review. *Environ Res* 142:51-60.
- 9 Marie C, Vendittelli F, Sauvart-Rochat MP (2015) Obstetrical outcomes and biomarkers to assess exposure to phthalates: A review. *Environ Int*. 83:116-136.
- 10 Fierens T, Van Holderbeke M, Willems H De Henauw S, Sioen I (2013). Transfer of eight phthalates through the milk chain — A case study. *Environ Int*. 51:1-7.
- 11 US Consumer Product Safety Commission. (July 2015). Phthalates. <http://www.cpsc.gov/en/Business--Manufacturing/Business-Education/Business-Guidance/Phthalates-Information>.
- 12 US Food and Drug Administration (July 2002). FDA public health notification: PVC devices containing the plasticizer DEHP.

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062182.htm>.

13 US Food and Drug Administration (December 2012). Limiting the use of certain phthalates as excipients in CDERregulated products.

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm330792.htm>

September 22, 2016 AMWA signs letter opposing the Hyde Amendment

<https://www.amwa-doc.org/wp-content/uploads/2017/04/HR-3504-Hyde-Provider-Letter-9-22.pdf>

September 22, 2016

The Honorable Trent Franks Chair

Subcommittee on the Constitution and Civil Justice Judiciary Committee

2435 Rayburn House Office Building

Washington, DC 20515

The Honorable Steve Cohen

Ranking Member

Subcommittee on the Constitution and Civil Justice Judiciary Committee

2404 Rayburn House Office Building

Washington, DC 20515

Dear Chairman Franks and Ranking Member Cohen:

We, the undersigned medical and public health organizations, stand in strong opposition to H.R. 3504 and restrictions on insurance coverage for abortion such as those imposed by the Hyde Amendment. Both policies represent government intrusion into private health care decisions.

H.R. 3504 is a departure from current law. It injects politicians into the patient-physician relationship, disregarding a provider's training and clinical judgment and undermining her ability to determine the best course of action with her patients. Patients need and deserve access to compassionate and appropriate medical care. Every woman is unique and needs to be able to make the decision that is best for her and her family. But H.R. 3504 would impose criminal and civil penalties on providers in an attempt to discourage them from providing care, limiting access for their patients.

The disproportionate and harmful impacts of the Hyde Amendment on low-income women and women of color have been well documented.<sup>1</sup> The American Congress of Obstetricians and Gynecologists has called for the repeal of the Hyde Amendment and similar restrictions.<sup>2</sup> All patients deserve access to safe and legal abortion care, regardless of where they live or how much money they have. Coverage bans like the Hyde Amendment have stigmatized abortion and women who have abortions for decades. It is time for this marginalization to end.



Abortion is a safe and legal medical procedure in the United States. Abortion providers comply with existing laws and provide excellent care. Women seeking abortion care deserve the highest quality medical treatment based on their individual health circumstances. Both H.R. 3504 and the Hyde Amendment undermine these principles by attempting to put abortion care out of reach. We urge lawmakers to protect the autonomy and dignity of patients and stand against the insertion of politics into personal health decisions.

Sincerely,

American Congress of Obstetricians and Gynecologists  
American College of Nurse-Midwives  
American Public Health Association  
American Medical Student Association  
American Medical Women's Association  
American Society for Reproductive Medicine  
Association of Women's Health,  
Obstetric and Neonatal Nurses  
Association of Reproductive Health Professionals  
Gay and Lesbian Medical Association  
Jacobs Institute of Women's Health  
Medical Students for Choice  
National Abortion Federation  
National Alliance to Advance Adolescent Health  
National Association of Nurse Practitioners in Women's Health  
National Family Planning and Reproductive Health Association  
Physicians for Reproductive Health  
Planned Parenthood Federation of America  
Society for Maternal-Fetal Medicine

1 A. Dennis, R Manski, K Blanchard, Does Medicaid coverage matter?: A qualitative multi-state study of abortion affordability for low-income women, J. Health Care Poor Underserved (November 2014). Available at <http://www.ncbi.nlm.nih.gov/pubmed/25418228>. 2 ACOG Committee Opinion, Committee on Health Care for Underserved Women, Increasing Access to Abortion (November 2014). Available at <http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee->

October 7, 2016 AMWA provides comments in support of the Obama Administration's Title X rule.

Title X was started as a bipartisan supported statute and has proven to be a monumental public health success for women and their families.

Title X funded programs are extremely cost saving and help women control when and if they have children. Title X funds provide accurate sex education programs, treatment and prevention of STDs, and have been overwhelmingly beneficial to poor and uninsured women.

Fact:

- Title X provides funding for contraception and STD care- it CAN NOT pay for abortion services
- More than four million people rely on Title X
- Most of them have incomes well below the federal poverty line
- Approximately one-third of them receive care at Planned Parenthood health centers
- Greater than 95% of Planned Parenthood clinical services are to provide birth control, STD screening and treatment, and other preventive and primary care services like Pap tests, breast exam and mammography orders.
- Every dollar spent on Title X saves more than \$7 in Medicaid-related costs

State laws that prevent Federal Title X funds going to Planned Parenthood Clinics are medically unsound. These laws are causing a public health crisis which harms women and their families. We must stop and reverse this dangerous tide.

Laws defunding Planned Parenthood are purely ideological and politically motivated. Planned Parenthood has provided US women high quality, trusted, and comprehensive medical care for decades including safe, legal and accessible abortion care.

October 2016 AMWA supported

[AB 1954 - The Direct Access to Reproductive Health Act](#) – which removed unnecessary administrative burdens that cause delays in care by prohibiting health insurance plans from requiring enrollees to secure a referral prior to accessing time sensitive essential health services like birth control, STD/HIV tests and treatment, and abortion care  
[SB 999 – Annual Supply to Contraceptives](#) – which provided women with consistent access to birth control by requiring Medi-Cal managed care and commercial health plans to cover up to a year's supply of FDA-approved self-administered contraceptives, like the pill, patch and ring.

October 17, 2016 AMWA joins members of the Patient, Consumer, and Public Health Coalition on supporting FDA's Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations or Sodium in Commercially Processed, Packaged, and Prepared Foods [Docket No. FDA-2014-D-0055].

<https://www.amwa-doc.org/wp-content/uploads/2017/04/Oct-17-Salt-Coalition-Comments-Final.pdf>

October 17, 2016

Division of Dockets Management (HFA-305)

Food and Drug Administration

5630 Fishers Lane, Rm. 1061

Rockville, MD 20852

**Comments of members of the Patient, Consumer, and Public Health Coalition on Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations or Sodium in Commercially Processed, Packaged, and Prepared Foods [Docket No. FDA-2014-D-0055]**

As members of the Patient, Consumer, and Public Health Coalition, we strongly support the Food and Drug Administration's voluntary sodium reduction goals. We agree that high sodium consumption "is a contributory factor in the

development of hypertension, which is a leading cause of heart disease and stroke.”<sup>1</sup>

We support FDA’s approach to lowering sodium content by avoiding “large, abrupt changes to individual products that might result in noticeably altered taste, greatly reduced shelf life, or other undesirable product outcomes.”<sup>2</sup>

We also support FDA’s “plan to monitor the levels of other nutrients (e.g., added sugars and saturated fat) ... to ensure that no broad trends emerge that negatively affect the nutritional quality of the foods.”<sup>3</sup> This has happened in the past when processed food manufacturers lowered the fat content of products such as cereals, yogurts, and snacks but then spiked the sugar levels to improve taste.<sup>4</sup>

The overall goal of this guidance is to reduce sodium intake in the general population to 2,300 mg/day from the current average adult level of 3,400 mg/day.<sup>5</sup> More than three-quarters of sodium that Americans consume is added when the food is manufactured or commercially prepared. By encouraging manufacturers, retailers and food service to reduce sodium, consumers have more access to healthier choices.

Research provides important information that should be used to help determine how best to reduce salt intake. A recent study by the U.S. Department of Agriculture found wide variation in the amount of sodium in similar types of products, which suggests that current food manufacturing practices and food preferences vary enough that sodium levels could be reduced in some types of foods relatively easily, and without reducing consumers’ enthusiasm for those products.<sup>6</sup> Others have examined the amount of sodium in the same or similar items from the same fast food restaurants in different countries or in the US over time. Again there were wide variations in the amount of sodium, suggesting that gradual changes in salt levels would not have a negative impact on consumer preferences.<sup>7 8</sup>

We support the FDA’s approach of using mg/ 100g as a standard way to monitor changes in the sodium in various foods independent of changes in serving size or other nutrient levels. However, it would be helpful for consumers and health professionals to also see what these changes mean in units that are found in the marketplace. This would increase transparency and allow outside monitoring.

We also want to encourage caution with the development of new or expanded use of food additives and other substances for food preservation or salty flavor. Any such chemicals or substances should be sufficiently studied to ensure that they do not have a negative impact on health in the short-term or long-term.

By making healthier options more available, consumers are able to choose foods based on what is important to them. We believe that many consumers will choose healthier options when they become available and as lower sodium levels become

the norm. Current initiatives by individual companies, New York City, and the United Kingdom have shown that large reductions in sodium content are attainable and attractive to consumers.

We reject the claim that some target levels for sodium might be low enough to be unhealthy. “More than 75 percent of the sodium in the average American Diet comes from salt added to processed foods,” according to the American Heart Association.<sup>9</sup> Consumers can continue to add salt to their food, if they choose to do so, since salt is plentiful and inexpensive in the United States. Currently, it is difficult for individuals to lower the sodium in their diet because the salt is added before the consumer purchases it. Reducing the sodium in processed and restaurant foods gives individuals greater control over the amount of sodium that they consume.

In summary, we strongly support the FDA’s effort to reduce sodium levels in foods, while monitoring foods to ensure that sodium reductions are not offset by unhealthy changes in nutrients such as increased saturated fat or sugar. The FDA must also ensure that methods to compensate for the reduction do not include substances that could harm consumers. Reducing sodium levels in processed and prepared food would provide consumers with more control over the amount of sodium they consume and thus make it easier for individuals to choose a lower sodium diet and lower the risk for hypertension, heart disease, and stroke.

American Medical Student Association  
American Medical Women’s Association  
Jacobs Institute of Women’s Health  
MRSA Survivors Network  
National Center for Health Research  
National Physicians Alliance  
Washington Advocates for Patient Safety  
WomenHeart: The National Coalition for Women with Heart Disease  
WoodyMatters

1 FDA DG (June 2016).

2 Food and Drug Administration (June 2016). Draft guidance, Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations of Sodium in Commercially Processed, Packaged, and Prepared Foods [Docket NO. FDA-2014-D-0055].

3 FDA DG (June 2016).

4 Nguyen PK et al (2016) A systematic comparison of sugar content in low-fat vs regular versions of food. *Nutrition & Diabetes* 6:e193.

5 FDA DG (June 2016).

6 Ahuja, JKC et al (2015) Sodium content of popular commercially processed and restaurant foods in the United States. *Preventive Medicine Reports* 2:962-967.

7 Dunford E et al (2012) The variability of reported salt levels in fast foods across six countries: opportunities for salt reduction. *CMAJ* 184(9):1023-1028.

8 Rudelt A et al (2012) Fourteen-year trends in sodium content of menu offerings at eight leading fast food restaurants in the USA. Public Health Nutrition 17(8):1682-1688.

9 American Heart Association (December 8, 2015). Processed Foods: Where is all that salt coming from?

[http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/PreventionTreatmentofHighBloodPressure/Processed-Foods-Where-is-all-that-salt-coming-from\\_UCM\\_426950\\_Article.jsp#.V\\_VryOArIdU](http://www.heart.org/HEARTORG/Conditions/HighBloodPressure/PreventionTreatmentofHighBloodPressure/Processed-Foods-Where-is-all-that-salt-coming-from_UCM_426950_Article.jsp#.V_VryOArIdU)

November 11, 2016 AMWA urges Congress to provide increased funding for research and services for Alzheimer's and other dementias.

<https://www.amwa-doc.org/wp-content/uploads/2017/04/LEAD-Coalition-FY-2017-Omnibus-Congressional-Appropriations-Letter-Senate-11-11-16.pdf>

<https://www.amwa-doc.org/wp-content/uploads/2017/04/LEAD-Coalition-FY-2017-Omnibus-Congressional-Appropriations-Letter-House-11-11-16-1.pdf>

November 14, 2016 AMWA signs letter urging Prometric to provide appropriate accommodations to candidates who are pregnant or breastfeeding at the time they are taking exams at Prometric facilities.

[https://www.amwa-doc.org/wp-content/uploads/2017/04/PrometricLetter\\_FINAL.pdf](https://www.amwa-doc.org/wp-content/uploads/2017/04/PrometricLetter_FINAL.pdf)

December 2, 2017 AMWA sends letter opposing the 21<sup>st</sup> Century Cures Act

<https://www.amwa-doc.org/demcoalitionletterprotesting21stcenturycures12-2-2016/>  
December 2, 2016

The Honorable #{Fname} #{Lname}  
United States Senate  
Washington, DC 20510

Dear Senator #{SalutationName}:

We are writing to urgently express our strong opposition to the newly revised 21<sup>st</sup> Century Cures Act, both in terms of the process of trying to pass a bill without adequate time for public debate, and for specific provisions in the bill that would harm patient safety. The undersigned nonprofit organizations represent members of the Patient, Consumer and Public Health Coalition, which includes more than 6 million healthcare providers, public health experts, and consumer and patient advocates.

Passing a complicated health bill in the rush of a lame-duck session is always problematic. Passing a 996-page bill that was negotiated behind closed doors and includes provisions that were never voted on before represents the kind of legislative sausage that the world's greatest deliberative body should reject.

While the bill includes some positive measures, the most important ones – funding for the National Institutes of Health (NIH) and the Opioid bill that

previously passed – **are not guaranteed in this legislation.** Unlike the earlier version of the 21st Century Cures Act that was passed in 2015, the funding is not mandated in the new version. The funding would need to be approved by Congress every year, which would be a challenge given appropriations concerns of the Republican majority in both houses and the opposition to this funding that has already been expressed by the Heritage Foundation.

In exchange for the **hope of additional funding**, the bill contains dangerous measures that would lower safety and approval standards for drugs and medical devices at the Food and Drug Administration (FDA). That’s why Senator Warren called the funding a “fig leaf. “ This bill would put all patients and consumers at risk.

For example, the bill pressures FDA to approve new medical products on the basis of “surrogate endpoints” instead of patient health and survival. A [new study](#), published in a journal of the American Medical Association this week, shows the danger of that kind of change. The study found that most newly approved cancer drugs do not help patients live longer or have a better quality of life. In fact, patients taking the most expensive cancer drug in the study (\$170,000 per patient) did not live longer than patients taking placebo and felt significantly worse. And yet all 17 ineffective new cancer drugs are still being sold, contributing to the skyrocketing cost of health insurance and undermining the financial viability of Medicare. [An editorial](#) in the same journal points out how this harms patients and our healthcare system.

The Accelerated Approval for Regenerative Advanced Therapies (Sec. 3033) makes it much easier for experimental stem cell treatments to be approved by the FDA without adequate testing to ensure their safety. Stem cell treatments are promising, but they are still highly unpredictable. Patients have become blind as a result of bones growing in their eyes, and disabled as a result of mucus growing in their spines, for example. This section of the bill was not passed as part of previous Cures legislation and has not been subject to a Congressional hearing or thoughtful debate. It is in the bill because it has been promoted by extensive campaign contributions. Patients will be harmed and the development of effective stem cell research will be delayed if these treatments are sold to desperate patients before they are adequately studied.

Several other provisions in the bill would also drastically lower standards for the approval of prescription drugs and devices. For example, it would allow FDA to rely on companies’ summaries of their study results, instead of requiring the FDA to review the data itself, as is current law when companies want to sell drugs for new indications (treatments). It also encourages the FDA to make approval decisions based on “real world evidence” that is not necessarily scientifically sound. The FDA currently reviews and scrutinizes scientific data provided by companies, which is necessary to make sure the benefits outweigh the risks for any approved indication. Providing summaries would also reduce information

about the possible risks to particular demographic groups, such as women or patients over 65.

The bill also allows off-label promotion of medical products under certain circumstances. This reduces or even eliminates the incentive for companies to conduct scientific research to prove that their products are safe and effective for new indications.

Another section of the so-called “Cures” bill would allow antibiotics to be approved based on minimal evidence of safety and effectiveness through a “limited population” approval pathway. The bill would not require that the antibiotics be studied on the target population that the new drugs would be approved for. In other words, it is possible that the antibiotics would not meet the urgent need that they are intended for. Unfortunately, these antibiotics could then be widely advertised and used by patients who are not likely to benefit, and could be seriously harmed by them. In the long run, that would contribute to antibiotic resistance.

The medical IT section of the bill would deregulate electronic medical records and decision support software. A study by the National Center of Health Research (NCHR) found that these types of health IT devices can cause life-threatening problems when they miscalculate incorrect drug dosages for chemotherapy drugs and other treatments. The [Breakthrough Devices](#) (Sec. 3051) encourages shorter and smaller clinical trials for medical devices. These smaller studies make it impossible to include sufficient numbers of women, men, seniors, and racial and ethnic minorities. Moreover, a recent study of high-risk medical devices found that the median number of participants is currently only [65 patients](#), which is already too few to adequately evaluate safety and effectiveness for both men and women, let alone for elderly men and women compared to young adults, or for minority populations.

**In summary, by lowering standards for approval of drugs and devices, and in some cases eliminating them, the bill would increase the cost of healthcare and pharmaceuticals at a time when such costs have become a grave threat to affordability of health insurance and to the survival of Medicare.** The implications for patients’ health and the affordability of medical care can’t be overstated. Researchers at the best medical schools in the country have shown that many ineffective and unsafe drugs are already being approved by FDA on the basis of the kind of preliminary data encouraged by 21st Century Cures.

For all these reasons, dozens of patient, consumer, physician, labor, and public interest groups, as well as former Members of Congress, have asked the Congress to delay consideration of the bill.

Thank you for your consideration of our views on this legislation. We must

ensure that patients can trust their drugs and medical devices to improve their health rather than harm it.

Sincerely,

National Center for Health Research  
American Medical Student Association  
American Medical Women's Association  
Annie Appleseed  
Association for Medical Ethics (AME)  
Advocating Safety in Healthcare E-Sisters (ASHES)  
Breast Cancer Action  
Center for Medical Consumers  
Connecticut Center for Patient Safety  
Institute for Safe Medication Practices (ISMP)  
Jacobs Institute  
Mothers Against Medical Errors  
MISSD  
MRSA Survivors Network  
National Physicians Alliance  
National Women's Health Network  
Our Bodies, Ourselves  
Public Citizen  
Quinolone Vigilance Foundation  
TMJ Association  
Treatment Action Group  
Union of Concerned Scientists  
Washington Advocates for Patient Safety (WAPS)  
WomenHeart: The National Coalition for Women with Heart Disease  
WoodyMatters

*For more information, please contact Jack Mitchell at [jm@center4research.org](mailto:jm@center4research.org).*

December 4, 2016 AMWA writes letter of concern regarding California's Department of Pesticide Regulation draft regulations for pesticide use near schools.

December 4, 2016

Linda Irokawa-Otani, Regulations Coordinator  
Brian Leahy, Director  
Department of Pesticide Regulation (DPR)  
P.O. Box 4015  
Sacramento, CA 95812-4015  
Emails: [dpr16004@cdpr.ca.gov](mailto:dpr16004@cdpr.ca.gov), [brian.leahy@cdpr.ca.gov](mailto:brian.leahy@cdpr.ca.gov)

RE: Draft regulations for pesticide use near schools



Dear Director Leahy and Coordinator Irokawa-Otani,

The American Medical Women's Association (AMWA) is extremely concerned that DPR's draft regulations for pesticide use near schools and daycares do not adequately protect school children or staff from the health threats of highly hazardous drift prone pesticide applications, because the proposed buffer zones are far too small and apply for only a part of the day. The buffer zones need to be in place 24 hours per day and be at least one-mile wide. Additionally, counties must retain full authority to adopt stricter requirements based on local conditions.

As a professional association of medical providers, we have serious concerns about heavy agricultural pesticide use near local schools. We urge DPR to move swiftly to improve the draft policy to provide comprehensive protections for school children and staff from hazardous and volatile pesticides.

We are particularly concerned about the disproportionate exposure of Latino school children, a fact documented by the Department of Public Health (DPH) report released in 2014. Latino children are almost twice as likely as white children to attend schools near the heaviest agricultural pesticide use. DPR can rectify this by decreasing the risk of pesticide exposure at schools across the state. The DPH report also found soil fumigants and other pesticides that are known to cause cancer, reproductive system effects, harm to the brain and nervous system and respiratory effects being used in large quantities within ¼ mile of many California schools. The draft regulations allow for the continuation of these unjust conditions, as the threats from pesticide drift continue long after applications outside the 6 a.m. to 6 p.m. buffer zone period for most applications and 36 hour period for fumigations, and from applications beyond the insufficient ¼-mile buffer zone distance.

We recommend that DPR require one-mile protection zones (buffer zones) for pesticides of public health concern between fields where these pesticides are used and schools, childcare centers, school bus stops, and known school routes. Pesticides of public health concern include pesticides that show evidence of causing cancer, reproductive damage, harm to the brain and nervous system, asthma and other respiratory problems. Hundreds of thousands, if not millions, of pounds of these hazardous pesticides are currently used annually near schools and daycares in agricultural counties throughout California. Protection zones of ¼ mile are simply not adequate for health protection. The first comprehensive report of drift-related pesticide poisoning conducted by state and federal health departments, found that in eleven states (including California) 15% of the people impacted in pesticide drift incidents were over 1 mile from the pesticide application, so 85% would have been protected by a 1-mile buffer zone. Seventy-six percent of the cases occurred at distances over ¼ mile from the application site, so ¼-mile buffer zones would not help in most cases. DPR's own air-monitoring network has shown ¼-mile buffer zones to be inadequate. For example, the air monitor at Shafter High School in Kern County has registered

over the last four years average concentrations of the toxic fumigant Telone at 175% of DPR's previous lifetime cancer risk level of concern, which agency risk assessment experts continue to support. This despite 1/4-mile buffer zones for schools in Kern County and zero Telone applications within 1/4-mile of the school. UC Berkeley and UC Davis studies have linked prenatal brain-harming exposure to organophosphates to pesticide applications up to a mile away.

Second, no-spray protection zones around schools and daycares should be enforced at all times for fumigations, ground air blast, as well as for aircraft applications, because students, teachers and community members are often on school grounds for scheduled events and unscheduled activities when school is not formally in session. Furthermore, pesticides can evaporate off the crop plants for days and even weeks after they are applied, and pesticide contaminated dust can be blown onto school grounds and tracked into classrooms. Eight of the ten pesticides most heavily used within a 1/4-mile of schools persist in the environment for more than a week.

Third, counties need to retain full authority to keep and adopt stricter requirements based on local conditions. The draft policy requirement that schools, grower, and County Agricultural Commissioner all need to agree on stricter requirements around specific schools hampers county officials' ability to protect children. Some counties currently enforce school buffer zones during evening and weekend hours and have adopted buffer zones well beyond 1/4 mile for certain pesticide applications. Growers should not be given veto power over such added protections.

Finally, while these are our most urgent and pressing concerns, we also urge your department to devote resources and attention, in collaboration with other agencies and universities, to reducing the use of, and phasing out, the use of soil fumigants and other high toxicity, drift-prone pesticides and helping farmers obtain resources to assist with this transition. Through innovation in agriculture, we can help California farmers adopt cutting-edge practices and tools that keep agriculture prosperous.

We hope that with improvements to the draft regulations, you will continue your commitment to the state's children and to the success of our farmers.

Sincerely,

A handwritten signature in cursive script that reads "Eliza Lo Chin, MD".

Eliza Lo Chin, MD, MPH  
Executive Director  
American Medical Women's Association

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December 16, 2016 – AMWA signs on to letter supporting Dr. Francis Collins for Director of the National Institutes of Health (NIH)

December, 15, 2016

President-elect Donald J. Trump  
Presidential Transition Headquarters  
1800 F Street, NW, Room G117  
Washington, D.C. 20270-0117

Dear President-elect Trump,

The undersigned, nonpartisan, patient and research nonprofit organizations, and companies, are writing to respectfully urge your favorable consideration of Dr. Francis Collins to continue serving as the Director of the National Institutes of Health (NIH) in your Administration.

We strongly endorse the sentiments expressed in support of Director Collins by House and Energy Commerce Committee Chairman Fred Upton; Senate Health, Education, Labor and Pensions Committee Chairman Lamar Alexander; Senate Labor-HHS Appropriations Subcommittee Chairman Roy Blunt; and House Labor-HHS Subcommittee Chairman Tom Cole. As their December 2 letter to you states, Dr. Collins' "distinguished scientific experience, effective leadership skills, and longstanding relationships with Members of Congress, researchers, and advocates will service the Nation and your Administration well."

Under Dr. Collins' direction, NIH research has not only improved public health, but it has also had high rates of social and economic return. For example, the United States government's \$3.8 billion initial investment in the Human Genome Project, that Dr. Collins led, has resulted in nearly \$1 trillion in economic growth—a 178-fold return on investment—and more than 4.3 million job-years of total supported employment.

Dr. Collins himself recently expressed that it would be an honor to continue his service in your Administration. In an interview just last week, he stated that "If I were asked to stay on, I would consider it a privilege to do so."

Medical research has long been treated as a nonpartisan priority. As Dr. Collins so eloquently said in a 2010 Newsweek interview, "I think history would say that medical research has, throughout many changes of parties, remained as one of the shining lights of bipartisan agreement, that people are concerned about health for themselves, for their families, for their constituents."

We look forward to working with your Administration and Congress to ensure that the United States remains the beacon for medical innovation throughout the world.

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Thank you for considering our views, and we wish you and your family health and happiness in the New Year.

Sincerely,

Alliance for Aging Research  
Alzheimer's Foundation of America  
Alzheimer's Greater Los Angeles  
Alzheimer's Mississippi

Alzheimer's Tennessee  
American Association of Neuromuscular & Electrodiagnostic Medicine  
American Brain Coalition  
American Heart Association  
American Lung Association  
American Medical Women's Association  
American Society for Nutrition  
American Society for Radiation Oncology  
American Society of Clinical Psychopharmacology  
American Thoracic Society  
Argentum—Expanding Senior Living  
Association for Clinical and Translational Science  
Laura D. Baker, Ph.D. (Wake Forest University School of Medicine\*)  
Biogen  
Caregiver Action Network  
CaringKind, the Heart of Alzheimer's Caregiving  
Clinical Research Forum  
Coalition for Clinical and Translational Science  
Suzanne Craft, Ph.D. (Wake Forest University School of Medicine\*)  
Cure Alliance for Mental Illness  
Cure Alzheimer's Fund  
Cystic Fibrosis Foundation  
Dementia Alliance International  
Digestive Disease National Coalition  
Dystonia Medical Research Foundation  
Friends of Cancer Research  
GBS|CIDP Foundation International  
Laura N. Gitlin, Ph.D. (Johns Hopkins School of Medicine\*)  
Hadassah, The Women's Zionist Organization of America, Inc.  
Hepatitis Foundation International  
HIV Medicine Association  
Home Instead Senior Care  
Huntington's Disease Society of America  
Indiana University  
International Rett Syndrome Foundation  
Interstitial Cystitis Association  
Iona Senior Services

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International Foundation for Functional Gastrointestinal Disorders  
IU National Center of Excellence in Women's Health  
Janssen Research & Development, LLC  
Johns Hopkins School of Nursing, Center for Innovative Care in Aging  
Walter A. Kukull, Ph.D. (School of Public Health, University of Washington\*)  
LatinosAgainstAlzheimer's Network  
March of Dimes  
METAvivor  
National Alliance on Mental Illness  
National Alopecia Areata Foundation  
National Association of State Head Injury Administrators  
National Certification Council for Activity Professionals  
National Council for Behavioral Health  
National Patient Advocate Foundation  
National Stroke Association  
National Task Group on Intellectual Disabilities and Dementia Practices  
NephCure Kidney International  
Neurotechnology Industry Organization  
Northeastern University  
OWL-The Voice of Women 40+  
Pulmonary Hypertension Association  
Stephen Salloway, M.D., M.S. (Alpert Medical School of Brown University\*)  
Scleroderma Foundation  
Sleep Research Society  
Reisa Sperling, M.D. (Department of Neurology, Harvard Medical School/Brigham and Women's Hospital and MGH\*)  
StopAfib.org  
Rudolph Tanzi, Ph.D. (Department of Neurology, MGH/Harvard Medical School\*)  
The Association for Frontotemporal Degeneration  
The Gerontological Society of America  
The Marfan Foundation  
The Michael J. Fox Foundation  
Geoffrey Tremont, Ph.D., ABPPCN (Alpert Medical School of Brown University\*)  
R. Scott Turner, M.D., Ph.D. (Department of Neurology, Georgetown University\*)  
Unite 2 Fight Paralysis  
UsAgainstAlzheimer's  
U.S. Hereditary Angioedema Association  
Wisconsin Alzheimer's Institute

\* Affiliations of individual researchers are for identification purposes only and do not necessarily represent the endorsement of affiliated institutions.

cc: The Honorable Fred Upton; The Honorable Frank Pallone  
The Honorable Lamar Alexander; The Honorable Patty Murray  
The Honorable Roy Blunt  
The Honorable Tom Cole; The Honorable Rosa DeLauro  
The Honorable Tom Price

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