Aspartame, OTC birth control pill, MMR & COVID vaccines with Andrea Garcia, JD, MPH

AMA Update covers a range of health care topics affecting the lives of physicians, residents, medical students and patients. From private practice and health system leaders to scientists and public health officials, hear from the experts in medicine on COVID-19, medical education, advocacy issues, burnout, vaccines and more.

Featured topic and speakers

In today’s AMA Update, the FDA approves an over-the-counter birth control pill and the WHO labels aspartame a possible carcinogen. AMA's Vice President of Science, Medicine and Public Health, Andrea Garcia, JD, MPH, also discusses the latest vaccine news, including the low rate of measles vaccination in the UK and when the next COVID shot will be available. AMA Chief Experience Officer Todd Unger hosts.

Speaker

- Andrea Garcia, JD, MPH, vice president, science, medicine & public health, American Medical Association

Transcript

Unger: Hello and welcome to the AMA Update video and podcast. Today we have our weekly look at the headlines with the AMA's Vice President of Science, Medicine and Public Health, Andrea Garcia in Chicago. I'm Todd Unger, AMA's Chief Experience Officer, also in Chicago. Welcome back, Andrea.

Garcia: Thanks, Todd. It's great to be here.

Unger: Well, Andrea, let's start with big news of the week. And that was the FDA's approval of an over-the-counter birth control pill. Tell us more about that?
Garcia: So last Thursday, the FDA approved an oral contraceptive called Norgestrel. It's also known as Opill for over-the-counter sales. And that makes it the first-ever hormonal contraceptive pill available in the U.S. without a prescription. Opill is known as a mini pill. And that's because it only contains one hormone, progestin, in contrast to the combination pills that contain both progestin and estrogen.

According to the manufacturer, the pill is expected to be available in stores and through online retailers early in 2024. We do know that there aren't going to be any age restrictions. But what we don't know yet is how much the pill is going to cost, which, will, of course, directly impact access. We should know that by sometime this fall.

Unger: So an over-the-counter birth control pill, that is big news. Give us more details on just how big a deal this is?

Garcia: Well, assuming it's affordably priced and covered by insurance, this could significantly expand access to contraception, especially for young women, for teenagers and for those who have difficulty getting to a physician for a prescription. It's also been shown to be extremely effective at preventing pregnancy when taken correctly. Even more effective than condoms and other nonprescription contraception that is currently available.

With nearly 50% of pregnancies in the U.S. being unintended, and the Supreme Court's decision that overturned that national right to an abortion last year, the accessibility of contraception has become an increasingly urgent issue.

Unger: The AMA's been pushing for this for a long time even before the SCOTUS decision. What was the response to this news?

Garcia: Well, as you said, the AMA has been pushing for this for years. In a statement, our AMA President, Dr. Ehrenfeld, called this approval a monumental step in providing broader access to safe and effective reproductive health care for millions of patients. While requiring an office visit to begin birth control is an unnecessary hurdle, we do still urge patients to retain those relationships with their physicians and stay up-to-date on screenings. We also continue to urge the FDA and HHS to consider a variety of oral contraceptive options for over-the-counter use.

It's important for patients to have options when choosing the type of birth control that works best for them. And we hope that this is just the first of several to be approved.

Unger: And we'll keep following that story. Thank you for the update there. Andrea, another major headline this week was about aspartame. What's the news there?
Garcia: Yeah, so also last Thursday we saw the World Health Organization's International Agency for Research on Cancer label aspartame a possible carcinogen. Specifically, the agency said that recent studies suggest that aspartame may be linked to a higher risk of liver cancer. I think before people begin throwing out their diet sodas, I think it's important to note that not everyone is in agreement here. A different agency within the WHO, called the Joint Expert Committee on Food Additives, said that it is not going to change its guidance for how much aspartame can safely be consumed in a day, saying the substance was not shown to absorb into the bloodstream.

The FDA's also weighed in and they said it disagrees with that agency's conclusion and that the studies that support classifying aspartame as a possible carcinogen to human was based on significant shortcoming. Dr. Francesco Branca, the director of the WHO Department of Nutrition and Food Safety says the big takeaway here is somewhere in between. People who consume high amounts of aspartame should consider switching to water or other unsweetened drinks. But these results do not indicate that occasional consumption poses a risk to most people.

Unger: So that is a little bit of confusion there. And even that term "possible carcinogen," what does that actually mean?

Garcia: So, the New York Times actually did a pretty good job of helping to put that in perspective for the public. Possibly carcinogenic to humans, it's a category that includes more than 300 viruses, chemicals or occupational exposures, certain pickled vegetables, engine exhaust, some types of human papillomavirus and working in dry cleaning can also fall into these same IARC categories. By contrast, alcoholic beverages, pollution, tobacco and processed meats fall into the classification carcinogenic to humans. Overall, the data on artificial sweeteners is lacking so it's difficult to say how much can be consumed or if one is better than another, or if you're better off with sugar altogether, which also we know has its risks.

In that same New York Times article, there was a medical oncologist who said to think about it this way, in terms of lowering cancer risk, people should think first about other factors that may make them more susceptible, like obesity, as well as alcohol and cigarette use.

Unger: Absolutely. Well, that's good to know. Let's switch to something I think we have a lot more data on. And that's vaccines. In fact, we spoke last week to Dr. Peter Hotez, a noted vaccine expert, about the growing anti-science aggression. And now we're beginning to see the fallout of misinformation at least in Europe. Andrea, tell us more about what's going on there?

Garcia: So we saw the UK Health Security Agency come out with a warning that London is now at risk for a major measles outbreak. I think it's important to keep an eye on this, because as we saw with COVID, what's happening in Europe can be a signal for what could happen here. Immunologists are saying that London could see anywhere between 40,000 and 160,000 new measles cases, which would likely lead to thousands of hospitalizations and dozens of deaths if MMR vaccination rates don't
We know that measles is not something to be taken lightly. It can get serious and lead to complications especially in young children and those with weakened immune systems. The CDC says 1 to 2 in 1,000 children infected will die from measles. And we know that a larger number will experience serious complications. And that can include things like intellectual disabilities and hearing loss.

**Unger:** So those are huge numbers. Obviously, preventable. How does a situation like this happen?

**Garcia:** Well, this is a direct result of low vaccine uptake, which is likely due to misinformation. The article points out that susceptibility is particularly high among 19 to 25-year-olds. And their parents were likely influenced by the unfounded vaccine scare stories in the early 2000s, which were linked to fraudulent and discredited medical publications. Until now, this population had been protected by herd immunity. But to maintain herd immunity, the WHO has said that target vaccination rate has to be 95% uptake. And we know the UK right now is below that target with the uptake for the first dose of the MMR vaccine in children aged two years in England at about 85.6%.

That's the lowest level in a decade. And in some parts of London, that coverage for the first MMR dose at two years of age is as low as 69.5%. Measles is one of the most infectious diseases transmitted through the respiratory route. So in a population with no immunity, a single case can infect between 10 and 20 others. So this is something that could escalate pretty quickly.

The best form of protection is getting vaccinated. Measles is preventable, as you mentioned. And with two doses of the MMR vaccine, you are protected.

**Unger:** That is a very good reminder so that we don't find ourselves in the same situation here. Andrea, continuing on the topic of vaccines, what can we expect for the fall as we look ahead. Do we need another round of COVID shots?

**Garcia:** Well, it's looking that way. And we can expect a flu shot, of course. And older adults will also be able to get that RSV vaccine that we've been talking about for the first time. And federal health officials are hoping that widespread use of these three vaccine will head off another tripedemic of respiratory illness like we saw last winter. It's worth noting that all three—COVID, the flu and RSV—are likely to resurge this fall. People with insurance for all of these vaccines should be available for free.

And last Thursday, we saw the Biden administration announce a program to provide free COVID vaccines to uninsured Americans through December of 2024 after the government supply of shots run out this fall. The shots, which the government is purchasing at a discount, will be available to the uninsured at pharmacies and at 64 state and local health departments.
Unger: And Andrea, will the fall COVID shot be a new formulation?

Garcia: Yeah, so that updated COVID shots are going to be from Pfizer, Moderna and Novavax. All are designed to target that XBB.1.5 Omicron variant that currently is circulating and accounts for roughly 27% of our cases. The full recommendations for that vaccine will not be available until we see the FDA authorize the shot and the CDC recommend their use in the population. Federal health officials have also shifted how they are talking about these vaccines.

So we’re not talking about a primary series followed by boosters anymore. In fact, they’re not being referred to as boosters. The intent here is to steer toward that idea of a single annual COVID immunization with this latest version of the vaccine.

Unger: That is a big change. Andrea, when will the shots be ready?

Garcia: So they’re expected to be ready in late September or October. We’re also expecting the CDC to make some recommendations on how flu, COVID and RSV vaccines can be co-administered. If you recall, many people received COVID and flu vaccines together last fall. So we’ll look forward to seeing those recommendations when they come out from the CDC.

Unger: Believe it or not, fall is not far away. So we’re going to continue to follow that story as we get closer. Andrea, as always, thanks so much for joining us and appreciate your perspective. That wraps up today’s episode. And we’ll be back with another AMA Update soon. You can find all our videos and podcasts at ama-assn.org/podcasts. Thanks for joining us. Please take care.

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