

SPEECH

# Reducing the Burden of Chronic Disease

MARCH 29, 2018

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National Food Policy Conference

Washington, DC

*(Remarks as prepared for delivery)*

More than 630,000 Americans die every year from heart disease.

It's followed closely by cancer as the second leading cause of death in America, with another 600,000 Americans dying annually from cancer.

While we've made progress in reducing deaths due to cancer and heart disease -- in part due to reductions in smoking -- some of that progress is now being offset by the increasing problem of obesity.

We focus a lot of policy and resources on the development of innovative new treatments for these and other maladies.

Medical innovation, and access to life-saving treatments, has the potential to remedy afflictions like cancer and heart disease.

But these maladies often result from a lifetime of accumulated risk.

And while investment in new treatments and efforts to ensure patients have affordable access to medical innovations must continue, we can't lose sight of the public health basics – better diet, more exercise, and smoking prevention and cessation.

For instance, one of the most effective ways to beat cancer is through broad prevention efforts that reduce the number of people who are afflicted by it in the first place.

And one of the best ways to achieve this goal is to reduce smoking rates, thereby abating the leading cause of preventable death and disease in this country.

FDA took new steps to sharply reduce the use of cigarettes.

The comprehensive plan we announced last July includes actions to render combustible cigarettes minimally or non-addictive -- to keep more people from getting hooked to tobacco in the first place.

At the same time, we're also taking new steps to try and more rapidly transition adults who can't quit tobacco altogether, and still want to get access to satisfying levels of nicotine, onto products that may pose far less risk to individuals compared to continued smoking.

But like our efforts to reduce smoking rates; improvements in diet and nutrition offer us one of our greatest opportunities to have a profound and generational impact on human health.

And FDA has a critical role to play to help make this happen.

Improving the nutrition and diet of Americans would be another transformative effort toward reducing the burden of many chronic diseases, ranging from diabetes to cancer to heart disease.

The public health gains of such efforts would almost certainly dwarf any single medical innovation or intervention we could discover.

The American College of Cardiology estimated that 22.4 percent of all male deaths and 20.7 percent of all female deaths in 2015 were attributable to poor dietary factors.

The prevalence of obesity in adults increased from 33.7 percent in 2007-2008 to 39.6 percent in 2015-2016, and it increased in children from 16.8 percent to 18.5 percent over that same time period.

Even a small advance in the nutrition of a single individual, which might have only a limited -- although discernable -- impact on a person's individual risk for chronic disease, would have a massive impact once we aggregate all those small health gains across tens of millions of lives.

And I feel strongly that FDA can do more to assist the American public with creating healthier diets for themselves and their families.

Today, chronic diseases are the leading causes of death and disability in the U.S., and both chronic diseases and weight-related conditions raise health care costs, reduce productivity, and shorten lifespans.

Chronic diseases that were once rare in kids -- such as type-two diabetes -- no longer are. This should worry us all.

There are many contributing factors to this increase.

And while we can't solve them all, we know that improved nutrition can play an important role in addressing these public health problems.

There's clearly a lot of room for improvement.

We know that the typical American's eating habits are far from perfect.

About three-fourths of the population has a diet that's low in vegetables, fruits, dairy and healthier oils—foods that are important to good health. At the same time, most Americans exceed the recommended intake of added sugars, saturated fats and sodium.

While 97 percent of American parents believe that childhood eating habits determine children's health for their lifetime, only 17 percent say their child's diet is very healthful, according to the National Poll on Children's health. That same survey also found that nearly half of all parents have difficulty determining which foods are actually healthy.

As a parent of three young girls, I share in the challenges busy, stressed families encounter daily in encouraging healthy eating. I know that among the reasons for a poor diet are the challenges in accessing healthy foods and in knowing which foods offer more health benefits.

We have a real opportunity to reduce the burden of chronic disease through better nutrition. But this is something we can only tackle together, by making better choices easier.

All of us here today have an important role to play.

FDA regulates 80 percent of our country's food supply and we take this important role in our nation's health very seriously.

That's why, today, I'm announcing a comprehensive, multi-year Nutrition Innovation Strategy intended to better fulfill FDA's role.

This builds on the 2018 Strategic Policy Roadmap I released in January.

Our new strategy plan takes a fresh look at what can be done to reduce preventable death and disease related to poor nutrition.

We'll use our tools and authorities to create better ways of communicating nutrition information to consumers so they can be empowered to make good choices. And we'll advance new ways to make science-based claims that provide more incentives for food manufacturers to produce products with more healthful attributes.

We know that these steps alone cannot fully alleviate the obesity epidemic in this country. But combined with other efforts, these incremental actions can create a path forward to a healthier future.

## **Current Trends**

It's not all doom and gloom. There are some favorable trends when it comes to diets and nutrition that give us many new opportunities.

Consumers are more interested than ever before to learn about the food they eat. Expectations are high. Consumers are demanding more healthful options. And they want to know what is in the foods they eat.

I see these trends as a unique chance to empower individuals who are using nutrition to improve their health and the health of their families.

At the same time, we see a market that's responding to new consumer expectations. New products are appearing on supermarket shelves every day. This is a direct result of consumer demand.

For instance, consumers are seeking out foods that meet criteria like being minimally processed, lower in sugar, and produced with wholesome ingredients. At the same time, we're seeing widespread consumer interest in foods that were once considered "specialty" items

We see the growing availability of such products on store shelves. Small shifts in consumer habits can have a significant impact on public health.

Clear, science-based information is a central pillar to the work we do at the agency. It's also a driving factor in better consumer choices.

In a 2016 survey of more than 1,500 consumers, virtually all responded that it's important that brands and manufacturers they buy from are transparent about what is in their food and how it is made.

The survey also found that consumers value healthful ingredients four times as much as brand recognition.

The food industry is innovating to give people more of what they want.

Food manufacturers are reformulating products to boost fiber content, limit additives, and curb the amount of sodium and sugar.

Sometimes innovation is used to make healthful foods more convenient, such as "grab and go" pre-packaged salad combinations, yogurt packaged with fruits and nuts, or protein drinks.

Sometimes it's preserving taste, while reducing an ingredient consumers want to avoid.

Take salt, for example.

Food scientists can make salt crystals taste saltier for some food applications by simply changing their shape to increase surface area, allowing less sodium to be used.

Or take sugar.

Simply shifting some sugar to the outside of cereal, rather than being uniformly distributed throughout, can lower the amount of sugar without changing taste. Some manufacturers are using flavor boosters like vanilla, cinnamon and other ingredients to enhance sweetness.

Consumer demands have also spurred companies to change labels to match these trends.

Labels are being developed with more information about what's in the food, how healthful it is, where it came from, and how it was grown and prepared.

But these opportunities are not absolute.

And just as troubling, they're not universally realized.

We see people who are not taking equal advantage of these trends -- or more likely, don't have the same opportunities to access them.

While diet-related health concerns impact the majority of the American public, it's also important to recognize that disparities in diet and nutrition are exacerbating disparities in health, and contributing to growing gaps in our society – including those related to longevity.

These gaps too often break down along socioeconomic lines.

And the promising opportunities we see in some quarters of our food marketplace are not evenly distributed across our society.

Not every neighborhood even has a basic supermarket.

Identifying and encouraging food patterns that are consistent with the dietary guidelines, affordable, and appealing is also a priority to fight social inequalities in health.

It can be a prejudicial cycle.

We know that education levels — in addition to income or access to healthy food — can play a prominent role in dietary habits.

And we know that poor dietary quality is more common in people with lower socioeconomic status.

Childhood obesity can lead to negative health outcomes later in life, but it may also have more immediate impacts, like increased risk of Type 2 diabetes, increased school absences, and less effective school engagement – or stigmatization and bullying.

The persistence and even growth in health disparities mimics trends in nutritional disparities.

From 1999 to 2010, researchers have observed a steady improvement in the average quality of the American diet, as more people reduced intake of trans fat and reduced consumption of sugar sweetened beverages and fruit juices, while increasing consumption of whole fruit, whole grains, polyunsaturated fatty acids and nuts and legumes.

During this same period, however, family income and educational level were positively associated with healthy eating and the gap in healthy eating widened over time.

So those with limited educational and economic opportunity are also more likely to suffer poor nutrition. This, in turn, exacerbates the incidence of chronic illness. And the burden of chronic illness – with all of its associated costs and hardships -- can exacerbate poverty or make it harder to work or make a person more likely to become disabled.

These are complex problems.

But the complexity isn't an excuse for letting them persist.

We can focus our efforts on making it easier for parents and children to have access to nutritious, affordable foods.

Food access and improving understanding of good nutrition and its implications for health are keys to remedying these disparities in nutrition and health.

There shouldn't be one set of food opportunities for the affluent, and another for lower-income and working class families.

The genius of American innovation – and the market – can help solve these problems. American agriculture is one of the 20th Century's modern miracles. And America is the breadbasket to the world.

Our challenge is to help create more healthy choices and foster innovation and competition that can also make these choices more affordable.

We need to work on new ways to decouple chronic disease from socioeconomic status.

And nutrition gives us one opportunity.

Without reliable access to healthy food choices, people can't make positive changes to their diets. They can't pass on those healthy behaviors to their children. If certain eating behaviors reduce chronic disease, then some communities will continue to have disparities in critical health outcomes unless we increase access to healthy food.

It doesn't all start with poor nutrition.

And it certainly doesn't end there.

But nutritional opportunities – and the resulting health impact -- can be a big factor in dismantling other societal divides across generations.

So we need to do more.

And we need to remember that even as we take steps to expand opportunities for better food products, and offer people more opportunities to improve health, we also must focus on making sure that these opportunities are equally available across society.

And we need to remember that these public health efforts will serve many goals. That good nutrition is a fundamental opportunity.

My purpose for the Nutrition Innovation Strategy I'm announcing today is to take account of these challenges, and the potential opportunities.

I believe that FDA can make further improvements in public health by both empowering consumers with information and facilitating industry innovation toward healthier foods that consumers want.

And in the process, I think we can help address broader societal challenges.

If we want to see real change, there are untapped opportunities that we need to pursue. To achieve these goals, we need to take a hard look at our entire portfolio to evaluate where we can be most impactful.

To begin, we're opening a docket and are holding a public meeting this summer where we can advance proposals to modernize our approach to better protect public health while removing barriers to innovation.

To start that dialogue, I'd like to spend a few minutes outlining some of the ideas that we have been developing with the leadership of the Center for Food Safety and Applied Nutrition or CFSAN.

These efforts include work to modernize label claims, ingredient labels, and standards of identity, while also taking forward our ongoing efforts to implement the Nutrition Facts Label and menu labeling initiatives, and reduce sodium. These are just some of the new steps we're

taking.

## **Modernizing Claims**

Consumers have long been interested in finding easier ways to identify healthful foods by looking at the label when shopping for groceries.

Science-based claims can help people do that.

That's why we're looking at modernizing how we look at claims.

Claims are quick signals on food packages for consumers about what benefits a food or beverage they choose might have.

Claims can also encourage the food industry to introduce new products or reformulate existing products to improve their healthy qualities.

Food makers are going to focus their innovation on attributes that they can advertise to consumers.

If manufacturers can't make claims around the healthful attributes of food, then we'll see fewer products that have these benefits.

We'll see manufacturers focus more of their investment and innovation on things that they can talk about like taste and value.

And there will be far less emphasis on coming up with the features that can improve people's nutrition and health.

I believe there's more room for competition in the marketplace when it comes to the healthfulness of different foods people eat.

And we're pursuing new ways to incentivize that competition.

Health claims are one such tool.

FDA must modernize our approach in this area, while also playing an important role in ensuring this tool is effectively deployed.

These claims can show that a food component may reduce the risk of a health-related condition, such as the relationship between folate and the reduction in risk of a child being born with certain birth defects.

Qualified health claims are another example.



These are claims that are supported by some scientific evidence, but don't meet the significant scientific agreement standard -- for example, the relationship between consuming certain oils and the reduction in risk of coronary heart disease.

A food package might also have a nutrient content claim like "good source of calcium per serving."

It's in everyone's interest to have meaningful claims that consumers can understand and trust.

It's also important that FDA does not permit claims that could mislead people to consume more products that aren't helpful to their health.

That's why we're asking what more we can do to encourage meaningful claims that reflect the latest nutrition science and could spur industry to introduce products that qualify for those claims.

"Healthy" is one claim that we believe is ripe for change.

The agency has already signaled its intention to update the criteria for this claim and we've held public meetings and reviewed comments.

Having a one-word claim such as "healthy" that's based on current science would make it even easier for busy consumers, including me, to make choices that can help build more healthful diets.

Traditionally, we've focused primarily on the nutrients contained in food in considering what is healthy. But people eat foods, not nutrients.

This is why we're asking the important question of whether a modernized definition of "healthy" should go beyond nutrients to better reflect dietary patterns and food groups, like whole grains, low fat dairy, fruits and vegetables and healthy oils?

Broadening the concept of what it means to be healthy may also better meet consumer expectations and empower them to make better decisions.

Take a recent International Food Information Council survey, which found that nearly 60% of consumers define a healthy eating style as getting the right mix of different food groups.

As we broaden our message, we can't undermine the importance of nutrients in our health message. Availability of information about nutrients -- both those that we need to limit, such as added sugars and sodium, and those that consumers aren't getting enough of, like potassium, remains a core aspect of our role and nutrition strategy.

We know that today people are eating too much food.

But in too many cases, they still may not be consuming enough of certain nutrients to achieve a balanced diet.

We're keeping all these considerations in mind as we pursue rulemaking to update the definition of "healthy" so it's based on nutrition criteria and food considerations that are more up-to-date than those being used for the current definition.

We also need to do more to help consumers see this information.

So, we'll also consider how to depict "healthy" on the package so that consumers can easily find it, particularly when they may not have the time or the skills to examine all the information on a food package.

To address this, we've had discussions about whether there should be a standard icon or symbol for the word "healthy" that everyone could use on food packages.

We'll be soliciting stakeholder input on whether this would be useful.

We also plan to seek input on other possible changes to our nutrient content claims and other types of claims that could facilitate innovation to promote healthful eating patterns.

We want to understand which claims would be the most useful to consumers to help them make good choices. And which would help -- and not hinder -- industry efforts to reformulate for healthier options.

In keeping with the enhanced focus on dietary patterns and food groups rather than only single nutrients, we're also interested in exploring claims for products that offer food groups for which American diets typically fall short of recommendations.

Examples include whole grains, low-fat dairy, fruits and vegetables and healthy oils.

Ultimately, we want to structure claims in a way that signals that a product contains a meaningful amount of these food groups.

As another action step, we'll streamline our process for reviewing qualified health claims we receive from industry.

We have a number of these in the queue right now, and they take a significant time to review. We need to consider how to enhance the efficiency of this review process.

For instance, we want to be able to triage these requests according to public health significance and to prioritize the review of those that are the most meaningful and science-based.

One example of how such claims can make a difference is manufacturers' ability to use a qualified health claim linking early peanut introduction in certain infants to a reduced risk of developing a peanut allergy.

Our intention to prioritize those qualified health claims that are most likely to have a health benefit, and that are based on the strongest science would encourage industry to submit their strongest, most significant, claims for review and to discourage submission of claims with little value.

This way, we can focus our resources on more quickly advancing the claims with most public health relevance.

Another claim we're frequently asked about is "natural."

In late 2015, we sought feedback from consumers and the industry on whether FDA should define and regulate the word "natural" on food labeling. More than 7,600 comments came in, and we've reviewed them. It's clear that consumers increasingly want to know what is in the food they eat and whether it is "natural."

We recognize that consumers are trusting in products labeled as "natural" without clarity around the term.

Just like other claims made on products regulated by FDA, we believe the "natural" claim must be true and based in science.

At the same time, we know that there are wide differences in beliefs regarding what criteria should apply for products termed "natural" -- and some of those criteria aren't based on public health concerns.

We'll have more to say on the issue soon.

### **Modernizing Ingredient Labels**

A second prong of our plan is to re-evaluate the ingredient information on food packages.

Consumers want "clean labels" that are readable and understandable.

Manufacturers are taking this consumer preference seriously, and FDA has a role here as well. We're considering what changes could make ingredient information more consumer friendly.

In addition to readability, this includes considering whether simpler alternative names for certain ingredients could be used so they are more understandable. For example, we could consider whether use of the name "vitamin B6" for "pyridoxine" and "vitamin B12" for

“cyanocobalamin” might help people better understand what’s in their food. As always, public health implications will be included as we consider whether simpler names for ingredients could be used.

One such proposed change is in front of us right now.

We’ve been petitioned to allow the use of alternative names for “potassium chloride” – to make it clear that this product is a salt -- and we’re actively considering this request.

The petitioner argued that some consumers associate the term “chloride” with chlorine bleach and consequently avoid foods that have “potassium chloride” in the ingredient list.

The petitioner urged FDA to consider how naming might encourage industry to replace some sodium chloride with potassium chloride, which could provide public health benefits.

### **Implementing the Nutrition Facts Label and Menu Labeling**

In addition to the new labeling work on modernizing claims and ingredient labeling, we need to finish our work on menu labeling.

We recently issued a draft guidance document that provides flexibility on how the menu labeling requirements can be implemented.

It shows restaurants and covered establishments how to provide calorie information on menus in ways that meets various business models.

We’ll soon finalize that guidance.

And beginning on May 7, 2018, consumers can walk into these covered eating establishments across the country and know at a glance how many calories are in the foods they order for themselves and their kids.

We’re also taking final steps on the new Nutrition Facts label—the first overhaul in more than 20 years.

Consumers are starting to have access to an updated label that’s based on current science, and provides more information to empower them to choose healthful diets.

We issued final regulations in May 2016 and we’ve proposed extending the compliance date for larger manufacturers to January 1, 2020.

Our work in food is a unique challenge for the agency because we’re creating a set of rules that has a broader range of stakeholders than the other areas we regulate. Our rules must consider the various components and challenges facing all elements of this diverse industry.

I understand that this is something we need to remain cognizant of, and it's why our public engagement needs to be robust.

I also know that it's crucial that we provide clear expectations so that industry can meet them. It's a priority to make sure we're communicating with stakeholders to ensure the standards they need to meet and guidance as to how to meet them can be utilized.

To these ends, we recently issued a number of technical documents on issues such as fiber and serving sizes to help manufacturers meet the requirements of the final Nutrition Facts Rule.

I also recognize that it is important for consumers to be able to effectively use the changes we make to food labels and that we take some new steps to help make sure that this information reaches consumers across the socioeconomic spectrum.

A few weeks ago, we announced we're launching a major educational campaign for consumers surrounding the new nutrition information that consumers will be seeing in the marketplace.

This will allow us to reach consumers directly through educational videos, social media campaigns and user-friendly websites to help them discern the relationship between the dietary choices they make every day and the impact on their own and their family's health.

The campaign will focus on the areas where we recognize that there are gaps in consumer understanding and use of nutrition information.

For example, we know that there seems to be a wide variation in people's knowledge of how many calories are needed in a day.

So we'll be providing educational resources that help people put calorie information into context when they see it.

In addition, we've heard that consumers want actionable tips to make healthier choices. So we plan on providing information such as "simple swaps" – like swapping out lemonade for a lower calorie seltzer with lemon. Where possible we'll target our educational efforts toward certain subgroups at greater risk for nutrition-related chronic disease.

We recognize that partners in this educational effort will be key to success. We're especially interested in working with groups that serve populations at greatest risk for nutrition-related chronic disease.

### **Modernizing Standards of Identity**

Another area where we believe FDA can facilitate innovation while protecting public health is related to food standards of identity.

Standards of identity are mandatory requirements related to the content and production of certain food products. For example, bread, jam, juices and chocolate all have standards of identity.

It's like a recipe for what must be in the food—or not in the food—for a company to use a certain product name.

The first standards of identity were set in 1939. Some provided for enriched foods to help eliminate a number of nutritional deficiency diseases. Others were designed to protect against consumer fraud.

They continue to serve an important purpose, letting consumers know what they're buying meets a certain standard in terms of what's in it.

But it's important that we take a fresh look at existing standards of identity in light of marketing trends and the latest nutritional science.

For example, the standards of identity for certain cheeses don't always permit the use of salt substitutes, which could be used to lower the sodium content of cheese.

And we've been asked to modernize the standard of identity for yogurt to support the many innovations occurring in this food category.

We'll also look to eliminate standards that may not be necessary.

Our priority, again, is public health, and flexibility is key.

We want to maintain the basic nature and nutritional integrity of products while allowing industry flexibility for innovation.

Protection against economic fraud still is critical.

But we also see a need for flexibility in standards that allow better public health outcomes by encouraging manufacturers to produce more healthful foods that are still affordable.

In addition to standards of identity, there are rules for naming and describing products.

I've asked the Center to issue a Request for Information to help guide us as we develop our approach to these areas.

## **Sodium Reduction**

Finally, I can't discuss a meaningful nutrition initiative without exploring what can be done to encourage the reduction of sodium in foods.

There remains no single more effective public health action related to nutrition than the reduction of sodium in the diet.

Excess sodium in the diet results in hypertension, which increases the risk of strokes and heart attacks. Researchers have estimated that reducing sodium intake by one-half teaspoon a day could prevent nearly 100,000 premature deaths a year, and up to 120,000 new cases of coronary heart disease, 66,000 strokes, and 99,000 heart attacks.

And, certain segments of our population such as African Americans are at greater risk for hypertension and develop it at earlier ages.

I'm committed to advancing the short-term voluntary sodium targets.

To provide guidance to industry, FDA proposed short-term, voluntary, draft targets for sodium reduction in foods that support reducing sodium intake to 3,000 milligrams per day from the current average intake of over 3,400 milligrams.

We intend to align our approach with the Dietary Reference Intake that's being conducted by the National Academies.

I believe we can build broad support for our approach.

FDA is currently working through more than 150 public comments that included important technical information that will enable us to improve on the targets to make them more practical and meaningful.

We plan to release the updated short-term targets in 2019, as well as continuing the dialogue on longer-term reduction efforts.

## **Conclusion**

Like our efforts to reduce tobacco use, our work in nutrition can do much to reduce the burden of chronic disease and the early death we see as a result of avoidable illness.

It can also help to break cycles of poor health, poor educational attainment, and complications from chronic disease that exacerbate burdens of illness and risk fracturing society along socioeconomic lines.

The burden of poor health falls heaviest on those who don't have access to all the tools of proper nutrition and health care resources.

It falls on families who have less disposable income, because they spend a greater share of their income on necessities like housing.


It falls on families who may consume higher quantities of low-cost calories -- which are often also low in nutrition -- because people can't afford or have reduced access to healthier options.

We need to focus our efforts in a way that can help reduce the disparities we increasingly see across society, and help focus the innovation and market competition we see in many segments of the food industry on families and children who could most benefit from it.

I'm committed to advancing our work in nutrition as one tool to help reduce health disparities, and improve the lives of all Americans, and to help every family live more free from the burden of preventable illness.

We'll need your help to advance these efforts.

We need you to weigh in and bring your best ideas to the table. And we look forward to your partnership as we advance this Nutrition Innovation Strategy and our shared purpose of public health.

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