

January 2018

## Summary of Strategic Policy Areas

Working in collaboration with the leadership of FDA's Centers, we identified the following four priority areas that will be the focus of additional policy activity in 2018:

- I. Reduce the burden of addiction crises that are threatening American families
- II. Leverage innovation and competition to improve health care, broaden access, and advance public health goals
- III. Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease
- IV. Strengthen FDA's scientific workforce and its tools for efficient risk management

While these areas are presented as separate concepts, like much of our work and our mission, the ideas embodied in these priority areas are not independent of each other. There are areas of overlap both between these priorities and with other aspects of our work at FDA. Achieving all of these goals will be reciprocally reinforcing, and complement other aspects of our mission.

### **I. Reduce the burden of addiction crises that are threatening American families**

#### **Reducing Misuse and Abuse of Opioid Drugs**

One of the highest policy priorities of the Department of Health and Human Services and FDA is advancing efforts to address the crisis of misuse and abuse of opioid drugs harming families.

Opioid addiction is claiming lives at a staggering rate. It represents one of the most pressing public health emergencies facing FDA. From 2000 to 2015 more than half a million people died from drug overdoses. Ninety-one Americans die every day from an opioid overdose. Overdoses from prescription opioids are reducing life expectancy in the United States.

Too many people are being inappropriately prescribed opioid drugs. When these prescriptions are written, they are often for long durations of use that create too much opportunity for addiction to develop. The amount of prescription opioids sold to pharmacies, hospitals, and doctors' offices nearly quadrupled from 1999 to 2010. At the same time, deaths from immediate-release opioid drugs have more than quadrupled since 1999.

We need to take steps to reduce exposure to opioid drugs by helping to make sure that patients are prescribed these drugs only when properly indicated, and that when prescriptions are

## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

written, they are for dosages and durations of use that comport closely with the purpose of the prescription. We also need to do more to facilitate treatment options and the development of therapies to address addiction as a disease. This means helping more people secure medication-assisted treatment (MAT) for addiction – involving the use of medications in combination with counseling and behavioral therapies – which requires us to break the stigma often associated with some of the medications used to treat addiction. It also requires us to find new and more effective ways to advance the use of medical therapy in the treatment of opioid use disorder.

Above all, FDA has a critical and unique role to play in the crisis of new opioid addiction – helping to reduce avoidable exposure to opioid drugs and reduce the rate of new addiction.

FDA has other pivotal roles to play in addressing this crisis. Among our science-based efforts, we will assist in the conversion of the market toward wider use of opioid drugs with improved formulations that are harder to manipulate and abuse; advance the development of drugs and devices that can treat pain and are less likely to lead to addiction; and create new paths for the development and approval of better treatments for addiction. This includes the development of both opioid agonists as well as antagonists. To drive wider adoption of MAT, we will also take additional steps to address the stigma sometimes associated with use of these drugs.

Additionally, FDA will strengthen its enforcement activities that target those who unlawfully market or distribute controlled substances and other unapproved drugs. We will step up our efforts aimed at the interdiction of opioids being illegally shipped into the United States.

### **Addressing Addiction to Nicotine in Combustible Cigarettes**

Another addiction crisis that is harming American families is caused by nicotine in combustible cigarettes. Nicotine addiction and tobacco use, especially cigarette smoking, persists as the leading cause of preventable death in the United States. The 50th Anniversary Surgeon General's Report in 2014 indicated that the death toll from tobacco was 480,000 people every year. At this rate, more than 17 million Americans will die avoidable, premature deaths by 2050 because of tobacco use.

Tobacco product regulation represents one of the Agency's greatest chances to save lives. In particular, examining the role of nicotine in combustible cigarettes must be part of a much broader strategy for how the FDA confronts the morbidity and mortality caused by smoking.

To pursue these public health opportunities, FDA is developing a comprehensive approach to the regulation of nicotine. This plan is premised on the need to alter cigarette addiction by rendering combustible cigarettes minimally addictive or non-addictive by regulating their nicotine levels, resulting in a reduction in the rate of smoking of combustible cigarettes to the low single digits.

## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

FDA's preliminary analysis suggests that, over the course of the 21st Century, the Agency's comprehensive new plan could prevent 8 million deaths, help tens of millions of people to not smoke who otherwise would have, and achieve hundreds of millions of life-years gained.

### Helping More Smokers Quit and Stay Quit

Nicotine, while not an entirely benign substance, is not directly responsible for the cancer, lung disease, and heart disease that kill hundreds of thousands of Americans each year. It is the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death – not the nicotine. As FDA moves forward with its comprehensive new approach, the Agency must also take a fresh look at products that can deliver satisfying levels of nicotine to adults who want access to it without burning tobacco.

With appropriate product regulation, new technology, and product innovation – including new medicinal nicotine products and electronic nicotine delivery systems (ENDS) – could present an opportunity for more smokers to quit combustible tobacco and stay quit. Our plan takes new steps to foster innovation in nicotine delivery, where such innovation could truly make a positive public health impact. It also makes sure that FDA has the foundational regulations to put products such as electronic cigarettes through an appropriate series of regulatory checkpoints.

In 2018, FDA will advance a series of rulemakings and guidances that begin the process of implementing this framework to put nicotine at the center of our regulatory efforts. As part of this comprehensive approach to the regulation of nicotine, in a world where FDA is already taking steps to consider how to regulate nicotine levels in cigarettes (and when combustible cigarettes are far less addictive) FDA has more opportunity to take steps to establish the foundational elements of a robust, science-based, and sustainable policy structure for properly regulating the non-combustible forms of nicotine delivery, including ENDS.

In a properly regulated market, these products would be available for adults who want to enjoy satisfying levels of nicotine through routes that may not pose all of the same risks as combusting tobacco. We will also take new steps to make sure these products are not available to kids. A key part of this plan also includes new efforts to enable medicinal nicotine products to play a more prominent role in helping smokers try to quit with help, to quit successfully, and to stay quit.

As a central part of these public health efforts, we will pursue additional ways to educate children about the harms associated with tobacco use through new public service campaigns. We will also take new actions to target the marketing of tobacco products to kids, and pursue additional partnerships with sister agencies to enhance the impact of our enforcement efforts.

### **II. Leverage innovation and competition to improve health care, broaden access, and advance public health goals**

FDA's mandate is to protect and promote the public health. Public health protection is the core of the Agency's fundamental, consumer protection role. Among other steps, it requires FDA to ensure that medical products are properly tested for safety and efficacy, are known to be of reliable quality, and are properly labeled. Promoting public health also requires the Agency to take steps that can help facilitate efficient access to beneficial, safe and effective, and innovative products that can address existing, novel, and emerging animal and human health problems.

Medical product manufacturers develop innovative products to earn premiums associated with new products that address unmet needs, offer better risk profiles, or use lower-cost production technologies. But after the expiration of patents and all relevant exclusivity, competition can lower prices of approved products and broaden access. Lower prices late in the life of medical products do not hinder innovation because they occur so much later than the decisions to invest in the research and development necessary to bring the innovative products to market. Thus, innovation – itself driven by competition – improves health care and promotes access by providing products that would otherwise be unavailable, while competition for older and once innovative products promotes access by lowering prices. FDA's policies foster innovation and competition to improve health care and access as a way of improving public health outcomes.

Incorporating the best science into our work and implementing policies that help new, beneficial innovations reach consumers efficiently – and at a lower cost – are key parts of FDA's overall public health mission to promote access to products that can help people improve their lives. The potential benefit of innovation spans the entire scope of our public health mission, including our vital work to better prepare our nation to respond to and protect the American people in the event of a public health emergency, whether naturally occurring or man-made.

Our efforts also include policies aimed at promoting innovation in manufacturing that can increase the reliability and safety of product supply, ensure the domestic supply of certain strategic products, and lower the cost of products through advances in how they are made.

#### **Improving Product Development and Strengthening FDA's Gold Standard**

Making the process for developing new, safe and effective, medical products more efficient can enable beneficial scientific advances to reach patients and animals more quickly. The efficiency of the development process is especially important when it comes to a lot of new technologies that have the potential to slow the progression of – and even cure – disease.

## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

Enabling the development of better ways of treating and avoiding disease can help improve outcomes and reduce overall health care costs. But if the cost of developing beneficial products is too high, or the regulatory process is unclear, it can deter innovation. This can be especially true if a drug or device is second or third to market. Yet this kind of product variety can be critical to patient choice and therapeutic diversity, as well as competition, access, and lower prices.

When the costs of developing new human and animal medical products are high, sometimes a drug or medical device targeted to uncommon conditions might not be developed at all. This can happen if the fixed costs of showing safety and efficacy are larger than the potential economic gain to the innovator of the new product. Making sure that the regulatory process is predictable, transparent, and scientifically modern can help reduce these fixed costs while improving our necessary assurances of safety and efficacy. A missed chance to promote public health through new innovation can hurt patients and increase overall health care costs. For these reasons, we should seek a predictable and efficient development process for innovative products while also taking new steps to strengthen FDA's gold standard for product review.

We are committed to new policies and guidance for product regulation in key areas of novel medical science, with the goal of creating pathways that allow beneficial new technologies to efficiently reach patients while strengthening our standards for product safety and effectiveness.

### **Promoting Generic Drug Competition**

FDA is also taking steps to encourage competition that can reduce patient costs by streamlining the process for bringing to market generic copies of novel drugs after all of the blocking patent and exclusivity periods have lapsed on a branded medicine. New medical innovations will not benefit patients and consumers if people cannot afford to access those opportunities.

We have a U.S. system of market-based pricing for innovative products to provide proper and strong incentives to entrepreneurs to take on the risk of these costly and highly uncertain endeavors. At the same time, Federal policies allow for vigorous competition once the patent and exclusivity rights have lapsed, as originally envisioned by in the 1984 Hatch-Waxman generic drug legislation. While this approach has worked well for many years, as part of our Roadmap we will take new steps to make sure this framework continues to support the interests of patients.

To advance these goals, we are developing policies to address a number of challenges:

First, the Agency is looking for places where branded companies may be taking advantage of FDA's policies in ways that prevent generic competition to prescription drugs. Among other steps, we will be issuing new draft guidance in the first quarter of 2018 on FDA's process for

## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

determining whether to grant a waiver of the requirement for generic firms to adopt a single, shared-system REMS with branded drug makers. We expect that this guidance will be helpful in situations where the negotiations of a single, shared-system is lengthy, complex, or otherwise creates a burden for stakeholders. We will also advance draft guidance on the development of shared-system REMS, to make the process for developing a shared REMS more efficient.

These steps are some of the measures we will take — as part of our broad strategy — to reduce “gaming” of FDA rules that can sometimes forestall timely generic entry after patent expiration.

FDA will also issue new guidance on how it intends to more efficiently handle citizen petitions, including so-called “blocking” petitions that are subject to section 505(q) of the FD&C Act. It is sometimes argued that these petitions block generic entry. While the record shows that citizen petitions have rarely delayed specific generic drug approvals, there is no doubt that the deadlines associated with 505(q) petitions can add to resource burdens on the generic review process. We expect our new guidance will allow for a more efficient approach to 505(q) petitions, and allow us to focus more reviewer resources on the approval of generic drugs.

Second, FDA is taking steps to address scientific and regulatory policy obstacles to the entry of some harder to copy or “complex” generic medicines. The FDA’s goal is to pursue translational science that can enable more efficient routes for demonstrating sameness in these settings.

Third, FDA is focusing on the overall efficiency of our generic drug review program, with the aim of continuing to build on our success in increasing its productivity. We need to continue to improve our ability to evaluate new generic applications in a timely way, and introduce efficiencies that keep the costs of filing generic applications low, as a way to encourage more competition.

By making sure that the barriers to generic entry are not unnecessarily inflated through outdated scientific standards or inefficiencies in the development process — while maintaining the FDA’s gold standard for quality, safety, and effectiveness — the Agency can help lower the barriers to generic entry, keep costs low for high quality generic products, ensure an adequate supply of critical generic medicines, and promote price competition. In 2018, we will build on the generic program’s strong foundation to see that our timelines and efficiency continue to improve.

FDA is also going to take new steps in 2018 to make the process for developing and approving biosimilar drugs more efficient. As part of these efforts, we will create better incentives for the adoption of safe, effective, and high-quality biosimilar drugs. These policies will be part of a new Biosimilar Innovation Plan (BIP) that we will advance over the coming year.

## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

As FDA improves its policies related to new product development, it is imperative that we balance increased access to lower-cost, generic medicines and biosimilars with the benefits of new product innovation. Competition plays a key role in reducing costs of products like prescription drugs, and enabling broader access to beneficial medicines. Greater access to effective drugs also helps advance the public health and lower overall health care costs by improving health outcomes and reducing the cost and burden of disease. Enabling access to safe and effective innovation that can promote better health is a critical part of FDA's mandate.

### **III. Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease**

#### **Leveraging Diet and Nutrition to Reduce Preventable Death and Disease**

FDA plays a critical role in promoting public health by empowering patients and consumers to make well-informed choices about their medical care and healthy living. Diet and nutrition are prominent tools for helping to prevent and manage chronic disease.

FDA works to ensure that consumers have access to the reliable, evidence-based information that they need to maintain and improve their health through diet and nutrition.

To achieve these goals, FDA will take new steps in 2018 to implement a comprehensive plan, incorporating a range of new efforts, to leverage dietary information to reduce the burden of disease through nutrition and encourage the development of more healthful food options.

#### **Leveraging Reliable Diagnostic Tools to Inform Consumers**

Empowering consumers to make better and more informed decisions also means promoting access to effective tools that can help provide reliable information about their health. These tools can include new technologies, such as digital tools and medical apps, which can provide up-to-date health information at the point of decision-making. We are taking new steps to make the development and review process for these novel technologies more efficient.

These goals also include new steps to help consumers more easily get access to reliable and accurate diagnostic information. This includes genomic data that can help consumers predict their risk for disease or their response to different interventions. Enabling these opportunities means also seeking better and less burdensome ways to reliably validate the analytical and clinical validity of laboratory-developed tests that consumers and providers increasingly rely on.

To achieve some of these goals, in some narrow cases we are considering complementary and voluntary new programs to encourage product developers to seek the benefits of FDA review

## **HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP**

through more efficient third-party validation and a new “Pre-Cert” review process. We also will be seeking to discuss with Congress additional legislative options to achieve some of these goals. Armed with reliable, analytically valid, and clinically meaningful, science-based diagnostic information, consumers can make more effective decisions about their lifestyles and health.

### **Advancing Digital Health Technologies**

By monitoring and managing chronic health conditions and dietary needs using consumer-directed mobile apps and other mobile health tools, or using medical devices to connect digitally with medical professionals, consumers can take more effective control of their care and their medical information and clinicians can provide better medical care. Well-validated, digital technologies provide a significant opportunity to achieve all of these and similar goals.

FDA will take new steps in 2018 across its regulatory portfolio to adapt its traditional approaches to regulation to better fit the challenges presented by new areas of technology. Digital health tools represent one such paradigm, and FDA’s Pre-Certification Pilot Program is one such effort.

Digital health technologies are characterized by highly iterative cycles of innovation. New software advances are introduced into products sometimes on a near-constant basis. The Pre-Cert pilot seeks to develop a more tailored approach to accommodate this rapid pace of digital innovation, while taking a risk-based approach to the Agency’s oversight of these products.

These and similar efforts are just some of the policies that the Agency will advance in 2018 to enhance the opportunities consumers have to use innovative tools and reliable, science-based information to make more informed decisions affecting their health.

### **IV. Strengthen FDA’s scientific workforce and its tools for efficient risk management**

The core technical, scientific, and clinical expertise of FDA’s people is the key to the Agency’s ability to bring innovative new products and technologies to patients, providers, and consumers. As the products that the FDA is asked to review become more complex and specialized, so do the technical demands on the Agency’s workforce. Our staff must remain current with the dramatic advances in science and medicine to meet the increasing demands that globalization and other trends place on our critical consumer and patient protection functions. At the same time, we must incorporate modern scientific tools into our programs to maintain FDA’s gold standard for product review, and make sure that our approach to managing risk are efficient and up-to-date.

#### **Improving Recruitment and Retention**

Several efforts are underway to build upon the strength and expertise of the FDA’s professional workforce. This includes conducting a comprehensive evaluation of the Agency’s hiring practices



## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

and procedures and an effort to modernize the process for recruiting, retaining, and supporting personnel to advance the hiring goals required to meet the Agency's evolving needs.

To improve our ability to attract and retain the most talented workforce, FDA is taking new steps to streamline its hiring practices and use new hiring and pay authorities in as robust a manner as possible. Some of these new compensation authorities were granted to FDA as part of the Cures Act. We will be taking steps to use these authorities to the broadest possible extent.

We will also take steps to bring greater alignment across FDA's different programs. For example, to foster greater internal collaboration between different functional areas we will continue to advance operational models that more closely align our pre-market review and field activities.

### Modernizing our Regulatory Toolbox

By adopting the most advanced science to inform our policies, and by emphasizing efficient risk management in all of our work, FDA can minimize the likelihood that its own requirements become an obstacle to the translation of beneficial scientific discoveries into practical solutions for patients, while continuing to strengthen its gold standard of regulatory oversight.

Toward these goals, among the many steps FDA will take: The Agency will embrace advances like predictive toxicology methods and computational modeling across our different product centers. We will also be making new investments in the FDA's high-performance, scientific computing.

These needs exist in the review of human and animal medical products as well as our oversight of food and other consumer products such as cosmetics. FDA's critical role in protecting the food supply was greatly enhanced by the passage of the Food Safety Modernization Act, which provides greater emphasis on preventing risk, as well as utilizing our enforcement tools when risks arise. It is a key element of FDA's risk-based approach to product regulation.

The Agency is working to enrich these regulatory and enforcement strategies to include new concepts that involve greater collaboration with our state and federal partners to implement efficient, risk-based oversight of human and animal food growers and producers.

Taken together, across all of the areas it oversees, FDA needs to make sure that the Agency's own policies and approaches keep pace with the sophistication of the products that we are being asked to regulate, and the opportunities enabled by improvements in science. FDA's regulatory tools and its technical expertise need to match the sophistication and resources of the products and approaches being adopted by well-intended sponsors. We must also have the resources to identify and thwart those who might deliberately try to advance dangerous substances and counterfeit goods. Science is giving FDA new ways to achieve these protections. Through a

## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

stronger FDA, we will leverage science to better protect American consumers and promote public health.

### Key Initiatives, Goals, and Actions

#### I. Reduce the burden of addiction crises that are threatening American families

Key Initiative	Goals	Actions
<p>FDA’s Opioid Policy Work Plan</p>	<p>Reduce the overall rate of misuse and abuse of opioid drugs; expand the opportunity for new product innovation to treat pain more safely, without addiction and advance therapies that can help effectively treat addiction</p>	<ul style="list-style-type: none"> <li>• Re-examine and modernize FDA’s framework for evaluating the pre- and post-market safety of opioid products based on risk and benefit considerations; including an evaluation of a product’s potential risks for illicit use or its potential for abuse</li> <li>• Address inappropriate prescribing of prescription opioids with new modifications to REMS programs that require, for example: training on non-opioid pain alternatives; training for prescribing related to immediate-release formulations of opioid drugs; and, broader training that covers more health care providers who help manage patients with pain</li> <li>• Support development of abuse-deterrent formulations of opioids by exploring new methods for analyzing, evaluating abuse-deterrent features; evaluating the nomenclature used to describe these abuse-deterrent features; facilitating development of science for generic development of these drugs; and, taking new steps to encourage the conversion of the market to effective, abuse-deterrent formulations</li> <li>• Finalize policies to enable the OTC availability of naloxone</li> <li>• Generate further opportunities for stakeholder input with public hearings and workshops on opioid issues while FDA explores new steps through innovations in regulation, packaging, and prescribing to reduce overall exposure to opioid drugs and address misuse and abuse. This could result in a new, comprehensive approach – using education, packaging, labeling and other tools – to encourage more appropriate prescribing and dispensing of opioid drugs</li> <li>• Advance policies to enable more product innovation in the development of non-addictive pain remedies; as well as the development of improved medication-assisted treatment (MAT)</li> <li>• Implementing a new and more robust approach to the oversight of illicit controlled substances and</li> </ul>

## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

		<p>foreign unapproved drugs imported into the U.S. through international mail facilities (IMFs). Among other things, the FDA will pursue new resources in these facilities and will expand its efforts through the formation of a new Enforcement Task Force</p> <ul style="list-style-type: none"> <li>• Launch a public campaign to drive more widespread, appropriate adoption of medication-assisted treatment and take new steps to address the stigma and other obstacles to more widespread availability and appropriate prescribing of MAT</li> </ul>
<p><b>A Comprehensive Approach to Reducing the Death and Disease Caused by Smoking Tobacco</b></p>	<p>Reduce death and disease caused by combustible cigarettes; put nicotine at the center of FDA’s regulatory efforts; support alternatives to cigarettes for adults who want access to nicotine through less harmful products, including medicinal aids; and protect kids from tobacco products</p>	<ul style="list-style-type: none"> <li>• Initiate a public dialogue surrounding nicotine through meetings, webinars and other public formats</li> <li>• Consider through rulemaking a nicotine standard for combustible cigarettes and a framework for addressing flavors in tobacco products to reduce initiation, addiction, and morbidity and mortality associated with smoking</li> <li>• Develop tobacco product standards, including standards for the regulation of kid appealing flavors, to reduce youth initiation and use of tobacco products like electronic cigarettes</li> <li>• Examine and develop new approaches to encourage innovation in medicinal nicotine replacement therapies (NRTs)</li> <li>• Continue youth-focused tobacco education efforts to reduce youth initiation; expanding FDA’s public service programs aimed at reducing youth use of tobacco, including ENDS</li> <li>• Establish an appropriate regulatory framework for new product innovations that could serve as less harmful alternatives to combustible tobacco, for adults who want to get access to satisfying levels of nicotine. Create a framework to properly evaluate their safety and potential benefits</li> <li>• Develop a more efficient approach to the regulation of provisional applications and how sponsors establish substantial equivalence for new and currently marketed tobacco products</li> <li>• Establish a working group with FTC to enforce against manufacturers that advertise kid appealing e-liquid flavors and step up efforts to target marketing of nicotine products to kids.</li> </ul>

## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

### II. Leverage innovation and competition to improve health care, broaden access, and advance public health goals

Key Initiative	Goals	Actions
Drug Competition Action Plan and Biosimilar Innovation Plan	Find new ways to modernize and adapt FDA rules and practices, to make sure that in places where Congress intended for there to be vigorous competition from generic drugs and biosimilars, these benefits are realized by consumers	<ul style="list-style-type: none"> <li>• Identify and address areas where branded firms are inappropriately impeding generic competition, including new guidance on how FDA determines whether to waive the requirement for a single shared REMS, as well as guidance on the proper design of shared-system REMS</li> <li>• Issue final guidance on product developers’ communication of information to payors about the economic consequences of their products which may promote value-based contracting</li> <li>• Continue to enhance development and review of complex generics, including operationalizing a new pre-ANDA program to expedite access to safe, high quality complex generic drugs</li> <li>• Maximize efficiency of generic drug program to reduce cycling and lower the time it takes generics to come to market</li> <li>• Establish an inter-agency working group to explore areas where FDA can more closely collaborate with FTC; issue new guidance to address FDA’s handling of 505(q) citizen’s petitions</li> <li>• Advance a set of policies to promote the more efficient market entry of generic competition for drug-device combinations. Develop new guidance to address and modernize the FDA’s current interpretation and adoption of Hatch-Waxman</li> <li>• Launch a comprehensive program to promote the development and adoption of safe, high-quality biosimilar drugs as part of a new Biosimilar Innovation Plan (BIP)</li> </ul>
Advanced Manufacturing Strategy Roadmap	Assure the availability of safe and effective medicines by modernizing the drug manufacturing methods to make the processes more reliable, efficient, and high quality	<ul style="list-style-type: none"> <li>• Establish an Emerging Technology Team to encourage and assist companies that want to implement new, innovative manufacturing technologies such as continuous manufacturing</li> <li>• Develop and publish clear regulatory standards for promoting wider use of continuous manufacturing of drugs and biologics</li> <li>• Advance guidance to help lower cost for compounders to become 503B outsourcing facilities and promote the development of a robust, high-quality outsourcing sector</li> </ul>

## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

<p>Medical Innovation Access Plan</p>	<p>FDA will cultivate new policies and guidance for product regulation in key areas of novel medical science, with the goal of creating pathways that allow beneficial new technologies to efficiently reach patients while strengthening FDA’s gold standard for product safety and effectiveness</p>	<p><b>New Drugs</b></p> <ul style="list-style-type: none"> <li>• Implement new streamlined orphan designation review template and expand orphan opportunities to new areas</li> <li>• Modernize the Office of New Drugs to ensure policies are rooted in the best science and management principles, and staff have the support and tools to achieve the public health mission</li> <li>• Develop a series of new, disease-focused medical product guidance documents to update and modernize approaches to clinical trial design and other aspects of the development of drugs targeting unmet medical needs. This will include a new suite of guidances and policies focused on the development of drugs targeting a group of serious neurodegenerative disorders</li> <li>• Update and modernize FDA’s approach to applying evidentiary standards for establishing safety and effectiveness for new drugs to more clearly define the role of real-world data and evidence, especially when it comes to evaluating post-market safety</li> <li>• Develop patient-focused drug development guidance to facilitate a more systematic approach to gathering and using patient perspectives to inform regulatory decision-making</li> <li>• Advance the use of <i>in silico</i> techniques to develop novel methods for creating models of virtual patient outcomes and modernizing FDA’s evaluation of patient benefit and risk</li> <li>• Develop and advance recommendations for an OTC monograph user fee program, to implement structural reforms to streamline and improve the timeliness of review activities, and foster innovation of OTC products</li> <li>• Advance a new regulatory framework (NSURE) to enable more drugs to be made available in OTC forms through the use of technology (such as medical apps) that can help patients better self-select when a product is appropriate</li> <li>• Explore the development of a policy framework under which an accelerated approval approach could be used to support marketing of a drug that demonstrates a survival benefit early in clinical development. The goal is to expedite availability of a therapy while the magnitude of the benefit it provides is being confirmed</li> <li>• Advance the use of new drug development tools and mobile technology for better capturing clinical trial data and the measurement of safety and benefit in pre- and post-market settings</li> </ul>
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## HEALTHY INNOVATION, SAFER FAMILIES: FDA'S 2018 STRATEGIC POLICY ROADMAP

		<p><b><u>New Biologics</u></b></p> <ul style="list-style-type: none"><li>• Advance a comprehensive framework to facilitate the efficient development of safe and effective gene therapy products</li><li>• Advance FDA's new framework for expediting the development and approval of safe and effective cell-based regenerative medicine products</li><li>• Expand FDA's oversight and enforcement with respect to cell-based regenerative medicine products, taking new steps to address products that are putting patients at risk and making false health claims</li><li>• Launch a new policy roadmap for the introduction of innovations in blood products and blood product testing</li><li>• Advance a new program to foster more efficient development of products intended for use in austere environments that can provide benefit to military personnel in deployed settings</li></ul> <p><b><u>New Devices</u></b></p> <ul style="list-style-type: none"><li>• Adopt a team-based approach to the regulation of medical devices that takes a lifecycle view of new products</li><li>• Install a new Total Product Life Cycle Office in CDRH to establish an agile infrastructure that adapts to future regulatory and scientific needs created by new technologies and minimizes organizational layers of review throughout the device life-cycle, achieving more efficient work processes and allowing employees to better leverage their knowledge of pre- and post-market information to optimize decision-making</li><li>• Advance a new approach to the review of medical device submissions through an alternative 510(k) pathway and a new framework to balance pre- versus post-market requirements targeted to significant unmet medical needs</li><li>• Advance a comprehensive plan to promote device safety using new tools and approaches to pre- and post-market oversight</li><li>• Develop and advance the use of <i>in silico</i> tools and models to evaluate device performance and patient outcomes as part of the Medical Device Innovation Consortium</li></ul>
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**HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP**

**III. Empower consumers to make better and more informed decisions about their diets and health; and expand the opportunities to use nutrition to reduce morbidity and mortality from disease**

Key Initiative	Goals	Actions
Nutrition Action Plan	Reduce preventable death and disease caused by poor nutrition by ensuring that consumers have access to accurate, useful information to make healthy food choices; foster development of healthier food options.	<ul style="list-style-type: none"> <li>• Issue practical, substantive guidance to advance implementation of the menu labeling regulations</li> <li>• Provide guidance for industry to implement the new requirements for updating the Nutrition Facts label</li> <li>• Launch a new public education campaign to help consumers maximize the public health benefits of the Nutrition Facts label and new menu labeling provisions</li> <li>• Initiate a new, comprehensive action plan encompassing steps FDA will take to advance policies that better leverage nutrition and diet as ways to reduce morbidity and mortality from disease. Among steps FDA will consider as part of this plan:               <ul style="list-style-type: none"> <li>○ Revising requirements for certain existing food label claims such as “healthy”</li> <li>○ Creating a more efficient review system for evaluating health claims on food labels</li> <li>○ Modernizing certain standards of identity to address current barriers to the development of healthier products while making sure consumers have accurate information about the foods they eat. Among other steps, FDA intends to issue a request for information to identify and help prioritize which potential standards of identity should be modernized based on their public health value</li> <li>○ Providing new opportunities to make ingredient information more helpful to consumers.</li> <li>○ Advancing guidance on dietary sodium reduction</li> </ul> </li> </ul>
Better Informed Patients	Pursue opportunities for patients to get access to information that can better inform medical decisions	<ul style="list-style-type: none"> <li>• Establish an Agency-wide Patient Affairs Staff to implement best practices for patient engagement across product centers</li> <li>• Establish new policies to make more information available from FDA’s product review process that can better inform consumers and providers; this includes safety information and the release of clinical study reports from drug reviews</li> <li>• Improve the consumer usability of the first fully searchable database for adverse event data reported to FDA</li> <li>• Advance new approaches for evaluating the analytical and clinical validity of diagnostic tests that can inform</li> </ul>

## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

		<p>consumers about their health and genomic information through new policies such as third-party review and firm-based certification</p> <ul style="list-style-type: none"> <li>• Improve reporting on issues related to women’s health through additional policies, guidance, and rulemaking, including better reporting of information from mammography</li> <li>• Launch a new pilot initiative to create a structure enabling the FDA to have its own capacity to more routinely update old generic drug labels with new safety and efficacy information</li> </ul>
<p>Digital Health Innovation Plan</p>	<p>Foster innovation in digital health technology tools that can help better inform and empower consumers</p>	<ul style="list-style-type: none"> <li>• Publish final guidance clarifying the digital health technologies that do or do not fall within the scope of FDA’s regulation or for which the FDA intends to exercise enforcement discretion</li> <li>• Advance FDA’s Software Pre-Certification (Pre-Cert) Pilot Program to develop a novel, firm-based approach for the efficient regulation of digital health technology sponsors that perform high-quality software design and testing</li> </ul>



## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

### IV. Strengthen FDA’s scientific workforce and its tools for efficient risk management

Key Initiative	Goals	Actions
Building a Strong FDA	Ensure FDA’s ability to bring innovative new products to consumers and use the latest science to improve public health by investing in the scientific and clinical expertise of the Agency’s staff and its policies	<ul style="list-style-type: none"> <li>• Conduct a comprehensive evaluation of the Agency’s hiring practices and procedures and modernize the process for recruiting, retaining, and supporting personnel to strengthen the hiring goals required to meet FDA’s evolving needs</li> <li>• Advance a new PDUFA Hiring Pilot and implement the new hiring and compensation authorities provided by the Cures Act that will give FDA the ability to bring on scientific candidates with specialized skills at more competitive salaries</li> <li>• Implement a new realignment of the Agency’s field activities with the program areas that FDA oversees to better integrate and coordinate inspection staff and review staff</li> <li>• Ensure that the Office of the Commissioner is structured and aligned for organizational efficiency and effectiveness: Conduct an assessment of the OC organization and reporting structures</li> <li>• Modernize FDA’s technology landscape to better serve stakeholder needs: Conduct a comprehensive assessment of FDA’s IT structure, with the goal of creating a future state that meets the needs of stakeholders in an efficient, effective way</li> <li>• Advance new tools and policies to improve the FDA’s ability to combat diversion and counterfeiting of drug products</li> </ul>
Scientific Computing Work Plan	Expand the use of high performance computing in order to modernize how the FDA evaluates clinical data to make product review more efficient and advanced	<ul style="list-style-type: none"> <li>• Increase FDA’s investment in supercomputing clusters and expand access to these resources to all review staff</li> <li>• Develop, in new guidance, updated statistical and computational methodologies as part of the medical product review process to evaluate clinical trial data using improved methodologies</li> <li>• Convene workshops, publish guidance documents and develop policies and procedures for leveraging modeling approaches</li> <li>• Conduct a pilot program on modeling approaches as a way to provide more collaboration with sponsors adopting these methods on model-informed drug development issues</li> <li>• Collaborate with external scientists and other stakeholders on the use of computational tools to develop rigorous natural history models that can help make clinical trial recruitment more efficient, especially as it relates to rare diseases</li> </ul>

## HEALTHY INNOVATION, SAFER FAMILIES: FDA’S 2018 STRATEGIC POLICY ROADMAP

<p><b>Strengthening Food Safety</b></p>	<p>Strengthen the safety of the foods that Americans eat by continuing to fully implement preventive controls and enhancing collaboration with farmers, food producers, and state and local regulators</p>	<ul style="list-style-type: none"> <li>• Advance adoption of preventive controls by food producers with new measures to ensure the feasibility of these methods while strengthening FDA’s tools and processes for protecting the public health</li> <li>• Establish a modern, science-based, efficient framework for FDA’s oversight of agricultural water to ensure standards and recognized testing methods are practical and effective</li> <li>• Ensure proper implementation of FSMA through new education, training, and outreach to farming operations, including by expanding On-Farm Readiness Reviews. To foster better collaboration with state regulators, FDA is also examining and potentially piloting a new approach to how the Agency issues observations made during on-farm inspections</li> <li>• Take new steps to ensure that farmers, food producers, and state regulators have the training needed to implement the Produce Safety and Preventive Controls rules</li> <li>• Expand FDA’s GenomeTrakr network domestically and internationally, building on its freely accessible database of genetic sequence information and metadata from food, environmental and human clinical isolates of bacterial pathogens to improve outbreak detection and to better understand how contamination can occur in order to prevent future outbreaks</li> <li>• Invest in new research to modernize toxicology testing across food safety and FDA’s other regulated product areas</li> </ul>
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