

# FOOD AND DRUG LAW JOURNAL

*Analyzing the Laws, Regulations, and Policies  
Affecting FDA-Regulated Products*

Drug Regulation 2056

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# Drug Regulation 2056

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*Imagine the year is 2056 and you walk up to randomly selected people on the street and ask, “What do you think about food and drug regulation?” People look at you quizzically. “Huh?” After getting a series of puzzled looks, shoulder shrugs, and “I do not know what you mean” responses, you wonder if this regulation has disappeared. Finally, you spot a wizened old greybeard and approach him. “Sure! I remember when drug regulation was a big deal,” he tells you. “When I was in my fifties, back around 2020, there was quite a public debate about making everybody responsible for assessing the benefits and risks of their own therapeutic selection. There were a lot of laws, regulations, and processes that did not make sense anymore. Of course, now we have new tools and knowledge that each of us uses to make health decisions. The quality of products is assured by manufacturers and in the marketplace. Defective products still can lead to liability but it happens very infrequently. Effectiveness and cost effectiveness of products and health approaches is well known, and low scores on these measures mean failure in the marketplace.*

## I. INTRODUCTION

Come back to the year 2005 and ask: Will change be faster or greater in the next fifty years than over the last fifty? If change comes faster, how different could food and drug regulation be in 2056? Most individuals and groups queried by the authors argued that change would come faster over the next decades. So, it follows that the past fifty years is an inadequate prologue for “reading the tea leaves” to see what the next fifty years will bring to food and drug regulation. This article takes a more speculative approach to regulation in 2056 by forecasting that many changes that have just begun—the World Wide Web, systems biology, and “predict-and-prevent medicine”—will be fully established by 2056. We will develop alternative scenarios for 2056 showing how what we currently think of as food and drug regulation could change given these forecasts.

We acknowledge that there are a wide range of plausible forecasts for these key forces and many other possible scenarios for regulation that could emerge. A full range of scenarios would include images of the best of times and the worst of times. We invite you, the reader, to make your own forecasts and develop scenarios for what you think is most plausible, but we have learned that the most valuable scenarios are those that most describe the best that could be. Imagining remarkable success is the first step toward accomplishing it. Our goal is to help readers who are interested in food and drug regulation see steps that can lead to great improvements in drug development. We will present an initial set of forecasts to highlight the range of changes that the next fifty years will see. These are followed by a discussion of market failure, major driving forces, a summary visionary scenario, and alternative scenarios.

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## II. FORECASTS ALONG THE WAY TO 2056

*Biological knowledge redefines medicine by 2029.*—The first maps of the human genome were followed by maps of most major species by 2010. By 2015, it became possible to sequence genes 5,000 times faster than in 2005. Reading individual genomes became an important part of medicine's ability to personalize care. Dr. Leroy Hood and his colleagues at the Institute for Systems Biology helped elucidate the networks of gene control systems and protein interactions to initiate predictive medicine in 2012. By 2020, a new understanding of health and disease emerged. Biological simulations could explain and predict how perturbations in dynamically complex, adaptive networks in individuals create most diseases. Since the 2040s, scientists have applied similar concepts to communities to predict and prevent the spread of disease. By 2056, medicine became capable of predicting most diseases for individuals, preventing most diseases and premature deaths, and letting people know when death was likely to come.

*International Classification of Disease (ICD) codes are abandoned by 2030.*—The old understanding of disease built on symptoms became so overloaded with subcategories that it lost its utility by 2015. Cancer alone expanded from approximately 200 recognized types in 2005 to over 2,000 in 2015, in order to account for genetic and proteomic variations in different tumors. The multiplicity of diagnostic categories needed to guide therapeutic decisions far surpassed the comprehension ability of any single doctor. Networks of doctors, pharmacists, scientists, and patient advocates formed around medical decision processes that became the norm by 2025. It is exceedingly rare in 2056 for medical decisions to be made by individual healthcare providers. Decision protocols demand the use of multiple perspectives from cross-disciplinary teams linked to global knowledge bases.

*The World Wide Web evolved from a "surface web" to a "deep web" by 2029.*—The interface between humans and computers shifted from the keyboard and mouse to an array of voice, motion, neural chips, and eye-movement readers for input. Knowledge tools made the Web far more important to science, medicine, and learning across all boundaries. Computer ontologies helped cooperative networks work through the "silo problems" that afflicted organizations and disciplines. By reducing the barriers created by specialized vocabularies and partially-shared assumptions, ontologies made collaboration across the Web easy. Natural language processing tools quickly spread to abstract knowledge from written and spoken words. Now, intelligent agents bring images to parts of the brain that can process visual information faster than language.

*Controlled clinical trials lose "gold standard" status by 2020.*—Clinical trials grew more expensive over the decades but did not answer questions that grew in importance over the years from 2005 to 2012. As the idea of personalized medicine took hold and the spread of electronic medical records accelerated, a variety of newer study designs and statistical approaches moved center stage in research. Adaptive trials with Bayesian statistics and large observational studies became more popular. Thousands of validated biomarkers were routinely identified using effective and cheap measurement. Devices for continuous monitoring made it easy to enroll and follow people in long-term studies. By 2022, it became mandatory in most countries to continue studies of drugs throughout their "lives" in the marketplace. Earlier movement to the marketplace was aided by *in silico* trials, which had become good enough in specific human population groups, with certain classes of compounds, to be highly predictive of safety and efficacy. It took nearly a decade of consistently accurate predictions from *in silico* tools, validated by

controlled clinical trials, before they were incorporated. Whether taking a drug or eating a food, since the 2020s individuals have personalized risk assessments that are created from myriad study designs across large populations.

*Combination therapy largely displaces monotherapy by 2035.*—The complexity of newly-understood health perturbations (formerly called diseases) was best addressed by precisely-delivered combinations of drugs to dampen or amplify dynamic change in networks, along with appropriate diet and supplements, physical activity, and stress management. The old understanding of disease (under which scientists once hoped that disease could be explained by a single cause or cured with a “magic bullet”) gave way to a more complex understanding. By the 2030s, individualized simulations allowed experimentation to establish the precise sequence and doses of drug combinations, food, activity, and other factors right for individuals. Many drugs now are given in homeopathic doses because it was discovered in the 2020s that there is an “information” component to a remedy that continues to be effective even in very small doses. Similarly, many foods are used to enhance health outcomes with the aid of predictive models based on an individual’s biology.

### III. WILL WE NEED REGULATION IN 2056?

#### A. Regulation and Market Failure

How much regulation of drugs and foods will be needed in 2056? Classically, governments regulate products and services because of a market failure. In some cases, products or their marketing are regulated ineffectively, such that regulation adds to the cost without offering real protection. In other cases, markets can work and negate the need for government regulation where there is competition and equality of power between producers and consumers. Where markets do not work to ensure safety (and in some cases effectiveness and cost effectiveness), government regulation is established.

As described more fully below, quality has three critical aspects: inherent, functional, and contextual. The future of drug regulation depends on the markets dealing appropriately with each aspect of quality; driving forces—within and beyond healthcare—will support this knowledge. The key drivers are the diffusion of knowledge and an increase in access to sources of knowledge. The axiom that “knowledge is power” implies that if the “deep Web” emerges by 2029, then consumers will have access to scientific and medical knowledge that will empower them. Consumers will know because trusted intermediaries will assemble knowledge that can be targeted for consumer decisions and tailored to their needs.

For 2005, *Consumer Reports* announced its “best buy drugs” program to advise consumers about drug cost effectiveness.<sup>1</sup> By 2029, this kind of advice from groups trusted by consumers likely will include genotype and phenotype information. Consumers will be able to personalize advice about foods as well as drugs to fit their values, their type of healthcare coverage, and their economic preferences, as well as their preferences for corporate social responsibility. In 2008, the International Standards Organization (ISO) will announce an approach to corporate social responsibility standards. By 2029, consumers will be able to know inherent quality (i.e., ingredients and potency of the product), functional quality (i.e., does it work for me, is it safe, and how relatively cost effective is it?), and contextual quality (i.e., in developing, manufacturing, marketing, and distributing this product, has the company met the standards supported by the

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<sup>1</sup> *Consumer Reports Magazine Launches ‘Best Buy Drugs’ Website*, MEDICAL NEWS TODAY (Dec. 10, 2004), at <http://www.medicalnewstoday.com/medicalnews.php?newsid=17610> (last visited June 3, 2005).

particular consumer and reported by one or more national or global reporting services?). This information will be accessed automatically when a person shops for and/or buys an item, or when a healthcare provider develops a prescription in 2056. In most settings, similar types of quality assessments will be applied locally to healthcare providers.

The history of food and drug regulation in the twentieth century can be seen as a series of efforts to protect the public, made more urgent by visible gaps in safety. Manufacturers provided adulterated products to ignorant consumers, which prompted early waves of the Food and Drug Administration's (FDA's) growth. In the middle part of the century it was the safety failure of a medication, Thalidomide, which led Congress to give FDA a more explicit mandate to regulating the safety and efficacy of medications based on "adequate and well-controlled" clinical trials.<sup>2</sup> This political reaction to a safety problem will persist, including the safety problems of Cox-2 inhibitors. In 2005, there were many calls for separating the safety assurance function from FDA—potential safety problems in foods (e.g., genetically modified organisms) as well as drugs lead many people to anticipate that history will keep repeating itself. Our forecast here is that companies will not be able to sell unsafe, defective, or ineffective products or services in a sustainable business. Consumers will not buy unsafe products from misleading companies (unless consumers consciously choose to do this).

The ability of doctors and patients/consumers to choose knowledgeably among available alternatives is critical to breaking the cycle of pent-up calls for reform, followed by a tragedy and then a reform. The history of major tragedies will repeat itself if safety knowledge does not improve and this improved knowledge is not disseminated more effectively. If companies suppress their knowledge of a drug's ability to harm people and if regulators do not discover the problem before the harm is done, then demand for regulation will increase. The only way for the drug and food industries to break the cycle of blame that leads to ineffective regulation is to take advantage of new technologies and methods for improving knowledge of risk.

In the years ahead, improvements may come from bio-informatics that can help personalize risk assessments. The ability to use *in silico* trials will provide greater capacity to predict effects in both populations and individuals. The anticipated widespread availability of electronic health records can integrate personal biomonitoring to enable reporting systems for continuous learning. This infrastructure will mean that after a drug is on the market, its benefits and its risks will be identified and made public in an ongoing way, based on the experience of large numbers of individuals. This knowledge will support more effective decisionmaking algorithms that are then used by physicians and consumers to assess the risks of both foods and drugs for specific individuals.

The twentieth-century cycles that dominated the relationship between producers and consumers in the marketplace and shaped regulation could end in the decades ahead. A knowledge revolution is likely to join other key forces to reshape drug regulation by 2056. Knowledge will be both deeper and broader. Like physics in the twentieth century, biology in the twenty-first century will deepen the knowledge of systems rules from molecular, cellular, tissue, organ, and organism levels, and broaden the knowledge so that it applies to communities and the ecosystem. This knowledge could be distributed widely through global networks and available for all by 2056, no matter what language, culture, or intelligence level. Thus, as discussed above, the primary regulatory mechanism will be smarter markets. There still will be a need for an enforcement authority to find and punish bad actors, but pervasive knowledge could make that a

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<sup>2</sup> Daniel Henninger, *Drug Lag*, in THE LIBRARY OF ECONOMICS AND LIBERTY: THE CONCISE ENCYCLOPEDIA OF ECONOMICS, at <http://www.econlib.org/library/Enc/Druglag.html> (last visited June 3, 2005).

residual—rather than a dominant—feature of drug regulation. The forecast here is that in these “smarter markets,” empowered consumers will get to decide what risks they want to take. By 2056, the knowledge of consumers, medical providers, and therapy developers/pharmaceutical companies will be supported by an infrastructure that empowers intelligent decisions about risk. This intelligence will stop large-scale safety failures, and over time will significantly lessen the need for government regulation of foods and drugs.

### *B. Other Key Forces Shaping Food and Drug Regulation*

In addition to the increased access to knowledge forecast above, the case for changing regulation by 2056 will depend on several other factors. These driving forces forecast to bring change by 2056 include:

*Understanding of Disease*—Well before 2056, most disease processes will be well understood, including the principal variants of the diseases that develop among individuals with various genotypes and phenotypes. For chronic diseases, changes during the earliest periods of the disease will be well understood thanks to molecular markers. These markers will both predict and monitor the progression of disease. The prediction of “health perturbations” will lead providers and consumers to pursue preventive approaches ever more tailored to the individual (considering that person’s genotype, values, culture, income and economic choices, learning style, and interest level). Routine biomonitoring by and for individuals, the electronic health record, and advanced consumer services from trusted intermediaries will support prevention strategies that combine both foods and drugs.

*Changes in Healthcare Delivery*—Conventional healthcare will become evidence-based, and electronic health records will enable this shift. Individual healthcare providers and provider systems will be judged on their success in preventing disease and healing individuals, as well as on their patient satisfaction scores. “Report cards” will be common. More sophisticated and effective self-care will emerge, supported by biomonitoring and significant home systems. For those individuals and families that still have a healthcare provider, the individual/family systems will interact seamlessly with those of the healthcare system. Success for healthcare providers will be measured more in terms of prevention than curing. Moving “upstream” will prove to be the most effective way for healthcare providers to score well on their “report cards.”

Healthcare’s shift to evidence-based approaches will merge with genomics and lead to customized care for individuals. It will mean integrating a wide array of conventional and alternative approaches to match an individual’s beliefs, genotype, phenotypes, and preferences, including ability and willingness to pay if the treatment is beyond the minimal level of defined benefits. A variety of community or public health interventions will prove to be successful and cost effective.

*The Nature of “Drugs” or “Medicines”*—Instead of single drugs, a wide range of small molecule chemical moieties; biologicals; biotechnology products; and drug, device, and food combinations will be used to bring order to biological systems that are perturbed by pathogens, behaviors, and genetic problems. The ability to develop combinations of drugs rather than single entities rests on new research and development (R&D) methodologies supported by an electronic infrastructure and a knowledge base that will emerge by 2029.

*Health State Focus*—Healthcare providers will address health far more knowledgeably. Much of the research focus will shift from disease states to health states in the second decade of this millennium. New findings about resiliency and hardiness will excite the public, and studies showing the extraordinary health that can be achieved will feed an interest in new research. In 2056, healthcare budgets typically will be divided evenly between dollars spent against disease (primarily prevention) and money spent to increase the health capacity of individuals, families, and communities. Many dramatic cures will become available along with the capacity to prevent many diseases. In some cases, there will be a single, identifiable cause when genetic damage is sustained or virulent pathogens emerge; for most conditions, successful prevention and treatment will result from a tailored mixture of systems knowledge and precisely targeted medicines, behavioral, and environmental changes.

*Function-Enhancing “Medicines”*—By 2056, a large portion of prescription medicines will be used for function-enhancement, including memory, sexual satisfaction, athletic performance, and emotional intelligence. The ability to combine central nervous system (CNS) medicines, therapy, and virtual reality simulations will lead to great strides in overcoming early-life trauma. One result could be a significant decline in depression. Another could be improved learning and educational performance among psychologically and physically abused children who, in an earlier age, would have become socio-paths.

### *C. Three Types of Quality Assurance*

With this complex set of forces shaping food and drug regulation, the focus of quality assurance will shift by 2056. Quality assurance of medicines will change in terms of how quality is defined, who defines it, and who assures quality. As noted above, the three types of quality—inherent, functional, and contextual—are interrelated, yet different. Distinct organizations typically are involved in assessing each type.

Inherent quality specifies that the medicine is pure, potent, of the appropriate strength, and contains no significant impurities. Pharmacopeias continue to take a lead in defining these inherent qualities. In the United States, since 1820, this function has been provided by a unique voluntary, nonprofit, nongovernmental organization—the U.S. Pharmacopeia (USP).<sup>3</sup> By 2056, a global pharmacopeia that will work virtually as a network will be created through the collaboration of the USP, the European Pharmacopeia, the Japanese Pharmacopeia, and others. Process analytic technology (PAT) will develop over the next two decades so that building quality assurance into the manufacturing process will displace the current approach of using reference standards.

Functional quality ensures safety, efficacy, and cost effectiveness. Since 1962, safety and efficacy have been FDA's responsibility but the market (e.g., large payers, pharmacy, and therapeutics committees for formularies) or other agencies with more economics expertise than FDA have judged cost effectiveness. By 2056, the definitions of safety and efficacy will be related to individuals rather than the public in aggregate. Smart markets will be ensuring functional quality and FDA will have only a residual enforcement role.

Contextual quality ensures that the production and use of a product conforms to larger societal values. Consumers, society, and the marketplace keep improving what is expected of products and services that are manufactured and sold; hence, contextual quality standards are a moving target. Contextual standards ensure that manufacturing,

<sup>3</sup> See U.S. Pharmacopeia, USP History, at <http://www.usp.org/aboutUSP/history.html> (last visited June 3, 2005).

distribution, sale, and/or use do not violate certain other values. These values are only beginning to be defined by international standards groups and consumer groups. Principal examples of these contextual standards are the ISO standards. The ISO 9000 series of standards focuses on ensuring quality management, including customer satisfaction and applicable regulatory requirements. The ISO 14000 series focuses on “environmental management,” seeking to minimize the harmful effects on the environment and to achieve continual improvement on its environmental performance. In 2004, the ISO reported that ISO 9000 and ISO 14000 were implemented by some 634,000 organizations in 152 countries.<sup>4</sup> The environmental management standards are an example of using certification in the marketplace to reward the pursuit and achievement of certain values (e.g., environmental protection).

ISO represents society, including manufacturers, agreeing to the standards that manufacturers should meet. In March 2005, an ISO committee began a three-year process of developing corporate social responsibility guidelines. ISO is seeking to “develop guiding principles with global relevance that will be useful to organizations worldwide in establishing, implementing, maintaining and improving the way they address social responsibility.”<sup>5</sup> So, in 2008 corporate social responsibility will be added to the contextual quality assurance, which ISO processes support.

Given that our societal choices about contextual quality assurance are evolving, what will be added by 2056? Over the next fifty years, a continued expansion of values will drive the evolution of ISO. Sustainability and equity will become the extension of ISO 14000’s current focus on environmental protection. Equity will become a growing part of the social responsibility standard. Equity, in this context, will focus on differences in health or well being that are unfair (or viewed as unfair) and avoidable. Human societies have changed their mind about what is fair and have eliminated slavery, ended apartheid, and expanded both women’s rights and minorities’ civil rights. By 2056, global equity will be added to the list of values to be supported by the marketplace and public policy.

### *1. Global Quality Assurance of Medicines and Drugs*

Quality assurance for foods and drugs will be assured globally and enforced nationally in 2056 by agencies such as FDA. As healthcare becomes more customized and the health modalities and healing systems of various countries become better understood, there will be more integration into global systems. The “best buy” consumer guides will be global in their operation, and will give consumers a range of choices among western, oriental, and ayurvedic approaches, to name a few.

### *2. Clinical Development*

By 2030, knowledge about biological effects of compounds will come largely from preclinical studies rather than clinical development. Nanolabs will measure cellular effects of different molecules. With millions of measurements taken from thousands of different cell types, scientists will be able to make powerful risk calculations before an experimental

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<sup>4</sup> Northeast Metrology Corp., Accreditation, ISO 9001:2000 Overview (last updated Dec. 28, 2004), at <http://www.vantek-corp.com/northeast/accreditation/iso90012000.htm> (last visited June 3, 2005).

<sup>5</sup> See International Organization for Standardization, ISO Prepares to Launch Development of Standard on Social Responsibility, at <http://www.standards.org.sg/files/vol11no5art3.htm> (last visited June 3, 2005).

compound is introduced into animals. Studies of absorption, distribution, metabolism, and excretion (ADME) will move *in silico* by the 2020s. Animals will be used sparingly as models for human response during subsequent decades, and rarely by 2056.

Clinical development itself will be hard to distinguish from medical utilization because the study of drug effects will be continuous throughout the time a drug is on the market. Methods for clinical studies will expand from the controlled clinical trial to a wide variety of study types. Each individual who takes a medicine (typically in combination with many others) likely will be part of multiple studies conducted continuously with a variety of monitors and web-based networks gathering intelligence and feeding back guidance. The same infrastructure that studies the response to drugs will reveal the effects of foods.

### *3. In Summary: Regulation by Governments*

By 2056, the need for government regulation for pharmaceuticals may remain to check commercial exploitation of false knowledge leading to bad health outcomes. The government level—federal, state, local, or global—that will play the lead role in such regulation is uncertain. It may well not be a national agency, such as FDA, that makes decisions about quality, given the potential for globalization and harmonization in a networked world where distributed expertise can be aggregated around any question or decision. Enforcement will continue to be needed “on the ground,” however, and that still will be a government role in 2056.

In a world reshaped by a deep knowledge of biology, it may be knowledge rather than drugs that will need to be regulated. The knowledge of the individual can be as important to the outcome as the knowledge of small molecules and biologics. In 2056, it may be feasible to assess “host health” in terms of an individual’s “resilience.” Then personalized models could simulate the probable effects of introducing a microdose of medicine, a new food, or any other perturbation. This would render irrelevant the notion of regulating drugs as single entities; instead, a network accessed by a consumer will perform the aggregation of risk knowledge. Perhaps governments will play a key role in regulating such networks, rather than foods and drugs.

## IV. A VISIONARY SCENARIO FOR 2056

Any individual considering a new medicine, food, or combination therapy in 2056 will connect to a web of knowledge sources that will provide a benefit-risk assessment for that decision. The decision still belongs to the individual and those most closely affected, but a world of scientists, medical professionals, ethicists, and people in similar circumstances will have weighed in on the decision. This world will know a great deal about the individual, including that individual’s values, genes, phenotypes, behaviors, and dreams. Before a decision is made, potential effects will be seen in models and simulations that are exquisitely tuned to the individual.

Transparency and depth of knowledge define medical use and food selection in this scenario. Regulatory enforcement comes into play only when hidden interests seek to exploit individual ignorance with false or misleading knowledge. In a world where the monitoring of public communication is pervasive, and where individuals monitor personal functions through an array of sensors and biomarkers, exploitation in the name of medicine quickly is made known. The global regulatory network is linked fully to local enforcement, and those who endanger health with false or misleading knowledge are caught quickly.

## V. ALTERNATIVE SCENARIOS

Over the next fifty years there are many other possibilities. We encourage you to consider your sense of the most likely and most visionary of these, given what you see as plausible and what you prefer. Below we add a few from our own perspective.

### *A. Bioterrorism Makes Drug Regulation Part of National Defense*

FDA had been under siege for the mortality and morbidity caused by the Cox-2 inhibitors and general public dissatisfaction when two terrorist incidents made it worse. First, global terrorists were able to hijack a drug counterfeit operation and then adulterate the counterfeit drugs with lethal properties that took their effect weeks after the pills were ingested; hundreds died, particularly elders. Then terrorists attacked the food supply, causing another wave of deaths. Simultaneously, inside a major pharmaceutical company, an engineer was able to put a toxin into a popular medication. FDA had little to do with any of this but Congress quickly transferred FDA from the Department of Health and Human Services to the Department of Homeland Security. All pharmaceutical manufacturers and biotechnology companies came under a strict regulatory regime. The industry became more concentrated over time, and is as dependent on the government as any defense industry.

The food industry retains more independence, but is subject to regulation that grows more burdensome each decade. The fear that food can poison begins with terrorists, but grows as more linkages to diseases and allergies are reported in the press. People learn just enough about genetic predispositions and individual responses to be concerned, but not enough to be empowered. Competing risk assessments flood the marketplace—some based on science, some on pseudo-science, and some on religious belief. As a result, safety testing became more stringent over the decades leading to 2056.

### *B. Postmarketing Regulation of Drugs*

Safety concerns led Congress to create the FDA Center for Safe Drugs (CSD) in 2007. Mandated postmarket drug safety studies provided alerts for drug safety problems, enabling the swift withdrawal of medicines found to cause adverse effects. R&D spending remained high, with prices rising even faster. The cost of getting a new drug on the market grew into the billions by 2014; drug prices escalated further until the public rebelled. In 2014, Congress reacted to the public's anger and passed a law further amending the Federal Food, Drug, and Cosmetic Act to adopt the successful model of the U.K. National Institute for Clinical Excellence (NICE). A series of studies by the U.S. NICE in 2020 led Congress to expand the mandate and change the name of FDA. The new Center for Safe and Effective Drugs (CSED) is empowered to withdraw drugs from the market and restrict prescribing to indications on the label. By 2025, the CSED merged with the former Centers for Medicare & Medicaid Services to gain full regulatory authority over drug prices.

The Center for Food Safety and Applied Nutrition, which regulates food and dietary supplements, also has become a dominant public health institution. The epidemic of obesity and diabetes over the first quarter of the century created a powerful demand for regulation. FDA began by focusing on labels to inform consumer choice, but by 2015 studies showed people still could not control their weight. FDA gained legislative authority in 2017 to regulate the content of prepared foods, to provide guidelines for the advertisement of foods, and to approve dietary supplements based on well-controlled studies.

## VI. CONCLUSION: YOUR CHOICE OF FUTURES

Which future is most likely for regulation? We invite the readers to consider the scenarios above and to develop their own. The most important scenarios are those that show a preferred future for drug regulation—that is, one more successful than seen in the past or present. Regulation in 2056 cannot be predicted accurately, but an image of regulation that radically improves public health can help compel and guide change. Our preferred image sees global knowledge informing personal choice that leads to smarter, healthier markets. What is your preferred future?