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CONTINUING THE RESTORATION AND TRANSFORMATION OF THE FDA

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INTRODUCTION

While I was Commissioner of the U.S. Food & Drug Administration (FDA), one of the most important collaborations my agency had with academia was our partnership with the University of Maryland. Whether it was in the area of food or collaborations in Critical Path initiatives or plans for academic partnerships at the FDA’s consolidated facility at White Oak, we were a part of Team Maryland. I want to particularly congratulate the University on the recent twenty-fifth anniversary of the Law & Health Care Program.¹

Recently, President Obama paid a visit to the National Institutes of Health (NIH) and announced a commitment of $5 billion from the economic stimulus package² for the purpose of research in cancer, Autism, and heart disease.³ As a former Director of the National Cancer Institute, and someone who has devoted his entire career to the elimination of the suffering and death due to cancer, obviously, I could not have been more pleased by that commitment. However, since it was part of the economic stimulus package, I am stunned and shocked that not one

³. Press Release, White House, supra note 2; see also Rich McManus, 'Scientist-in-Chief' Welcomed: President Obama Visits NIH to Tout ARRA Benefits, NIH RECORD, Oct. 16, 2009, at 1, 6, available at http://nihrecord.od.nih.gov/pdfs/2009/10162009_Record.pdf (relating the targeted programs and research projects that the new NIH funding will help to create).
dollar was allocated to the FDA—not one dollar of the $787 billion for economic
stimulus was allocated to bail out the FDA. 4

If one ranks federal agencies that are critical to our economy, one has to put
the FDA very close to the top of that list. If you do not agree, I suggest that you
check with spinach farmers in California and peanut farmers in Georgia, 5 and ask
drug and medical device developers about how critical the FDA is to their
economic survival.

Today, Washington is the epicenter of a nation-wide debate about the future
of health care in this country. 6 The American people are demanding a health care
system that assures they will have access to quality health care. 7 Access to quality
health care means care that is: available, affordable, and appropriate.

I. AVAILABLE, AFFORDABLE, AND APPROPRIATE

Once again, I am stunned and shocked that, in our entire health care debate,
no mention was made about the role of the FDA in assuring that quality health care
will be available, affordable, and appropriate for the American people. Yet, the
FDA is a critically important, if not the essential, element in each one of these
goals.

When one thinks of health care from the point of view of availability, one
must recognize that people are suffering and dying of a variety of diseases because
the health care they need simply does not yet exist. Such access will not exist until
the fruits of all the investment in discovery and development occurring in academia
and industry create products—products that will only become available when
cleared or approved by the FDA. 8

Will health care in the future be affordable? While the government tries to
control the price of health care, the single agency that significantly impacts the cost

(granting funding to various agencies and departments within HHS, but not to FDA).
5. See, e.g., Lyndsey Layton, Every Peanut Product from Ga. Plant Recalled; FDA: Toss Out
Anything Made in 2007-08, WASH. POST, Jan. 29, 2009, at A1 (discussing the 2009 salmonella outbreak
that centered around a Georgia peanut butter manufacturer); Jesse McKinley, Officials Narrow
Investigation After Finding Bad Spinach, N.Y. TIMES, Sept. 21, 2006, at A29 (discussing the E. coli
outbreak that contaminated spinach in 2006).
6. See David M. Herszenhorn & Robert Pear, Health Care Overhaul: Bill Passes Crucial Senate
Test, N.Y. TIMES, Nov. 22, 2009, at A1 (detailing the efforts of the entirety of the legislative and
executive branches in attempting to pass health reform).
7. See, e.g., Jeffrey M. Jones, Majority in U.S. Favors Healthcare Reform this Year, GALLUP, July
Gallup poll that found that fifty-six percent of Americans were in favor of Congress passing healthcare
reform legislation in 2009); Susan Page, Poll: Health Care Fix Is Welcome—But Not the Cost, USA
health-care_N.htm (discussing the same Gallup poll).
8. See, e.g., 21 U.S.C. § 355(a) (requiring FDA approval for the marketing of a new drug); id.
§ 360e(c) (defining the FDA approval requirements for certain medical devices).
of medical product development is the FDA. Regulation affects the timeline of discovery, development, and delivery, and the FDA can foster change through initiatives like Critical Path that can reduce the risk to product development.

Will health care be appropriate? What other federal agency will play a more significant role than the FDA in ushering in the era of personalized medicine? We must understand the performance of drugs—not in the population sense, as comparative effectiveness research will do—but in the context of the person. What other agency can create a pathway to integrate diagnostic and therapeutic platforms in a way that can assure the right treatment to the right patient for the right reason? What other Agency has a repository of data about the mechanisms of action of a drug that determines its benefit and risks in animals and humans? And yet, rather than invest in bioinformatics systems to acquire, collate, and mine this rich FDA registry data, we have committed $1.1 billion to initiate an effort in comparative effectiveness research, the results of which will have no practical application for many years to come. I am stunned that with the central role the FDA must play in the future of health care, assuring its future success is not part of our national debate.

We are not committing, nor are we discussing, a long-term, sustained effort to enhance the capacity and capabilities of this agency. At my confirmation hearing, Senator Kennedy stated at the opening that, with all due respect to NIH, the Centers for Medicare and Medicaid Services, and the Center for Disease Control and Prevention, no other federal agency is more important to public health than the FDA. And yet, in September 2005, when I arrived at the FDA, I found an agency

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on the verge of catastrophic collapse because of decades of neglect, coupled with an increasing burden of responsibility, and combined with an increasing volume and complexity of regulated products. It was on the verge of failing in its mission to both protect and promote the health of every single American. Four years ago, the FDA had to embark upon a process of radical change. The process had to incorporate two elements: restoration and renovation.

II. RESTORATION AND RENOVATION

The first and most critical challenge was to restore the capacity of the agency. The challenges were numerous: the shrinking and aging of the workforce, the decline in our ability to recruit talent and essential skill-sets, the ineffective and inefficient information technology (IT) infrastructure, and the need to develop modern science and technology tools for the regulatory process. The good news is that that capacity building is underway. We were able to significantly increase the budget by forty percent in FY09 when compared to FY06. 3000 people are being added to the workforce with new skills and perspectives, and an FDA fellowship program has been created. Changes that have occurred over the past few years have enabled the FDA to begin the process of restoring its capacity. Underway is a

13. Matthew Perrone, FDA's Brain Drain Clogs Drug-Approval Pipeline, ASSOCIATED PRESS, June 3, 2008 ("As companies siphon off FDA’s most experienced scientists they leave an increasingly leaner, less confident staff. . . . FDA's leadership is scrambling to recruit a new generation of food and drug regulators, as the average age of FDA's . . . work force reaches [fifty-four].").

14. Id.; see also Bridget M. Kuehn, FDA's Science Infrastructure Failing, 299 JAMA 157, 157 (2008) (describing the inability of FDA to maintain a sufficient scientific workforce as one of three key weaknesses that emerged following decades of inadequate FDA funding).

15. See Kuehn, supra note 14, at 157.

16. See, e.g., CRITICAL PATH INITIATIVE, supra note 10, at i (explaining that despite the advances in science in technology, the FDA saw a decline in the number of new and innovative products submitted for approval, which prompted the agency to develop the Critical Path Initiative as a national strategy to modernize the regulatory process).


complete revamping of the IT infrastructure—not simply replacing pre-Y2K servers, but for the first time creating a truly integrated, interoperable IT infrastructure. Now, across the entire agency, there will be a much greater opportunity to move data to information that creates the knowledge that informs regulatory decisions.

Many have had the opportunity to see the continued growth and development of White Oak and its new modern facilities, along with many changes that are occurring throughout the widespread FDA field offices. This now includes our ability to have the FDA Beyond Our Borders program with permanent FDA offices around the world, building regulatory capacity and expanding our ability not only to inspect but to build quality into the products that will eventually be used by American consumers. We have also continued the International Drug Regulators Summit, an annual meeting of the CEOs of mature regulatory agencies that was inaugurated by the FDA in 2006.

A sustained, committed, and ongoing effort to continuously nurture and build the capacity of the FDA must be continued. A one- or two-year infusion of funds is insufficient for the magnitude of this task. Just as we committed to a five-year plan to double the budget of the NIH, we need to commit to a strategic and business plan that sustains the growth and development of the FDA over many years, not just a few years. Building capacity is only the first step, and what the FDA most needs is the ability to enhance its capabilities, to address the challenges and opportunities of twenty-first century progress in the life sciences.

For 100 years, the FDA has been the world’s gold standard. In the twentieth century, it has served us extraordinarily well. But during the decades of neglect, there were decades of astounding, radical progress being made in the area of


The whole concept of health care has been revolutionized for the twenty-first century. The implications of the molecular metamorphosis of medicine will not only challenge the FDA with a growing portfolio of products, but also an incredibly increasing complexity and sophistication of those products. Whether its nanotechnology or regenerative medicine, we must face a realization that in the next century, we will see far greater integration of components and products into comprehensive solutions.

The reality is that if the FDA is going to achieve its mission, then we must commit to enhancing its capability. This will entail major change within the agency. It will require major change in terms of the philosophy that drives the agency. The agency has seen itself as a gate-keeper, but now it must be an agency engaged in the total lifecycle of products from the beginning of their discovery and development all the way through understanding their performance as they are used in practice. Beginning with a proactive agency-wide integrated plan to address a pandemic of *H5N1* and by accelerating many of the initiatives that are contained in *Critical Path*, the FDA has been making great strides in this area, providing the agency with greater opportunity to use regulatory science to transform the process of medical product development.

Enhancing post-market surveillance through initiatives like *Sentinel* will give the FDA the opportunity to engage in acquisition of information about the performance of medical products in large diverse populations, thereby enhancing its ability to detect circumstances of unexpected risk and benefit. These efforts are going to require major, sustained, and committed change within the agency itself. There needs to be an opportunity for the FDA to recreate itself but we must recognize the depth and magnitude of the kind of changes this will require in the


25. Andrew C. von Eschenbach, Comm'r, U.S. Food & Drug Admin., Remarks Before the National Press Club: FDA at a Turning Point: Meeting the Challenge of a Rapidly Changing World (Feb. 29, 2008), available at http://www.fda.gov/NewsEvents/Speeches/ucm051551.htm ("FDA can no longer be simply a gatekeeper assessing benefit and risk before allowing a product to be delivered to patients or the public, or to rely solely on inspections to verify quality. It must engage in the Total Life Cycle of the products we regulate whether it is food going from farm to fork or medical products from production to consumption.").


29. Id. at 5.
way in which the FDA actually does business. The agency must commit to a long-
term, scientifically rigorous program of process improvement.

This will require a process engineering approach that deconstructs the steps in
the regulatory pathway from initial concept approval to final regulatory decision
and subjects those steps to critical review to determine root causes of inefficiency
and ineffective regulation. Measurable outcomes must go far beyond user-fee-
derived timelines and must embrace the responsibility to rapidly bring life-saving
and health-enhancing products to people while assuring their safety and
effectiveness. We must also ensure a regulatory process that is transparent,
predictable, efficient, and rigorous. The regulatory process needs to undergo major
transition so that it is aligned with the nature and complexity of twenty-first-
century medical products.

The FDA has made strides, for example, in addressing the need to define a
pathway for products incorporating nanotechnologies and biosimilars; however,
there is much more on the horizon, including the regulation of complex integrated
products that incorporate therapeutic, diagnostic, targeting, and delivery
constructs.

CONCLUSION

The FDA must have these kinds of capabilities and must undergo this kind of
process change if it is going to be able to both protect and promote the public
health. We have to move forward in a sustained and committed way to ensure that
the FDA that was the gold standard of the twentieth century remains and continues
to be the gold standard of the twenty-first century. The work has begun, but the
work is far from over.

I no longer have the privilege of directly engaging in that effort, but I do, as a
former Commissioner, have the responsibility to continue to find ways to
contribute to that effort. I am asking you to continue your effort and determination
to sustain our nation’s effort to restore the capacity and capabilities of that
agency—an agency that must undergo a sustained systematic and systemic
revitalization if it will be able to assure the American people that it will promote
and protect their health and assure access to quality health care that is available,
affordable, and appropriate. I believe this is our most significant responsibility.

30. Brian Wilhelmi, Nanosilver: A Test for Nanotech Regulation, 63 FOOD & DRUG L.J. 89, 101-
103 (2008) (describing the FDA’s regulatory response to the relatively new field of nanomaterials).
31. Scott Gottlieb, Biosimilars: Policy, Clinical, and Regulatory Considerations, 65 AM. J.
HEALTH-SYS. PHARM. (SUPP. 6) S2, S2–S4, S7 (2008).
32. Susan Bartlett Foote & Robert J. Berlin, Can Regulation Be as Innovative as Science and
Technology? The FDA’s Regulation of Combination Products, 6 MINN. J. L. SCI. & TECH. 619, 619–22,