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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 & Heath 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 package[2] 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

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1. UNIV. OF MD. SCH. OF LAW, LAW & HEALTH CARE PROGRAM: 25th ANNIVERSARY CELEBRATION 1 (2009), *available at* http://www.law.umaryland.edu/faculty/conferences/conf91/program.pdf.

2. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, 175–78; Press Release, White House, President Obama Announces Recovery Act Funding for Groundbreaking Medical Research (Sept. 30, 2009), http://www.whitehouse.gov/the_press_office/President-Obama-Announces-Recovery-Act-Funding-For-GroundingBreaking-Medical-Research/.

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

4. *See* American Recovery and Reinvestment Act of 2009, div. A, tit. I, 123 Stat. at 116–27 (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 14, 2009, http://www.gallup.com/poll/121664/majority-favors-healthcare-reform-this-year.aspx (citing a 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 TODAY, July 14, 2009, at 1A, *available at* http://www.usatoday.com/news/washington/2009-07-13-poll-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.[9] 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.[10]

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,[11] 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.[12] And yet, in September 2005, when I arrived at the FDA, I found an agency

9. *See* Martin S. Lipsky & Lisa K. Sharp, *From Idea to Market: The Drug Approval Process*, 14 J. AM. BD. FAM. PRACTICE 362, 362–64 (2001) (explaining the arduous process of medical product review and the high associated-costs); James T. O'Reilly, *Losing Deference in the FDA's Second Century: Judicial Review, Politics, and a Diminished Legacy of Expertise*, 93 CORNELL L. REV. 939, 950, 955–56 (2008) (stating that an expensive FDA approval is required before a medical product enters the market).

10. *See* Lipsky & Sharp, *supra* note 9, at 364–66 (detailing the various phases of drug development required by federal regulations and policed by the FDA). *See generally* U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., THE CRITICAL PATH INITIATIVE: TRANSFORMING THE WAY FDA-REGULATED PRODUCTS ARE DEVELOPED, EVALUATED, MANUFACTURED, AND USED (2009), *available at* http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/CriticalPathInitiative/UCM186110.pdf [hereinafter CRITICAL PATH INITIATIVE] (detailing the various projects put in place by the Critical Path initiative to reduce risk in product development).

11. American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115, 176–77; *see also* Milton C. Weinstein & Jonathan A. Skinner, *Comparative Effectiveness and Health Care Spending—Implications for Reform*, 362 NEW ENG. J. MED. 460, 460–61 (2010) (discussing the impact of comparative effectiveness research on health care spending).

12. *Nomination of Andrew von Eschenbach and Paul Decamp: Hearing of the Comm. on Health, Education, Labor, and Pensions*, 109th Cong. 7 (2006) (statement of Sen. Kennedy, Member, S. Comm. on Health, Education, Labor, and Pensions), *available at* http://bulk.resource.org/gpo.gov/hearings/109s/30085.pdf ("[T]he Food and Drug Administration is perhaps the most important health Agency that we have in the United States of America, and probably in the world.").

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,[13] the decline in our ability to recruit talent and essential skill-sets,[14] the ineffective and inefficient information technology (IT) infrastructure,[15] and the need to develop modern science and technology tools for the regulatory process.[16] The good news is that that capacity building is underway.[17] We were able to significantly increase the budget by forty percent in FY09 when compared to FY06,[18] 3000 people are being added to the workforce with new skills and perspectives, and an FDA fellowship program has been created.[19] 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).

17. Andrew C. von Eschenbach, *The FDA Amendments Act: Reauthorization of the FDA*, 63 FOOD & DRUG L.J. 579, 584 (2008); *see generally* U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., FDA STRATEGIC ACTION PLAN: CHARTING OUR COURSE FOR THE FUTURE (2007), *available at* http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/UCM061415.pdf [hereinafter FDA STRATEGIC ACTION PLAN] (outlining strategic goals for FDA capacity building that began in 2007).

18. *Compare* Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act, 2006, Pub. L. No. 109-97, 119 Stat. 2120, 2147 (2005) (granting FDA $1,481,617,000), *with* Omnibus Appropriations Act, 2009, Pub. L. No. 111-8, 123 Stat. 524, 551 (granting FDA $2,038,964,000, an increase of 38% from 2006).

19. Press Release, U.S. Food & Drug Admin., U.S. Dep't of Health & Human Servs., FDA Launches Fellowship Program to Develop Pipeline of Scientists, Other Professionals (July 17, 2008), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116921.htm; *see also* FOOD & DRUG ADMIN., COMMISSIONER'S FELLOWSHIP PROGRAM: PROTECTING PUBLIC HEALTH THROUGH SCIENCE AND REGULATION (n.d.), *available at* http://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/CommissionersFellowshipProgram/UCM126544.pdf (presenting an overview of the fellowship program).

complete revamping of the IT infrastructure—not simply replacing pre-Y2K servers, but for the first time creating a truly integrated, interoperable IT infrastructure.[20] 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.[21] 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.[22]

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,[23] 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

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20. *See Statement Before the Subcomm. on Oversight & Investigations of the H. Comm. on Energy and Commerce*, 110th Cong. 2–3 (2008), *available at* http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/Testimony/OI/110-oi-hrg.061208.Acheson-Testimony.pdf (statement of David Acheson, Associate Comm'r for Foods, Food & Drug Admin., U.S. Dep't of Health & Human Servs.) (describing the varied program areas targeted by a $65 million plan to modernize FDA's IT infrastructure); FDA STRATEGIC ACTION PLAN, *supra* note 17, at 7–8 (listing a number of objectives to help modernize FDA's IT and regulatory structures through improved communication, collaboration, and access).

21. U.S. FOOD & DRUG ADMIN., CONSUMER HEALTH INFORMATION: FDA BEYOND OUR BORDERS 1, 2 (2008), *available at* http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm103044.pdf; *see also* Press Release, U.S. Food & Drug Admin., U.S. Dep't of Health & Human Servs., FDA Food Protection Plan Shows Significant Progress (July 2, 2008), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116917.htm (describing the various ongoing efforts, including the *FDA Beyond Our Borders* initiative, to prevent unsafe products from entering the United States).

22. Andrew C. von Eschenbach, Comm'r, U.S. Food & Drug Admin., Remarks at the Inaugural International Summit: The Challenges of Regulation in the World of Molecular Medicine (Nov. 16, 2006), *available at* http://www.fda.gov/NewsEvents/Speeches/ucm051822.htm.

23. Press Release, U.S. Dep't of Health & Human Servs., President Fulfills Commitment to Doubling NIH Funding (Jan. 26, 2002), http://archive.hhs.gov/news/press/2002pres/20020126.html.

science and technology.[24] 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.[25] Beginning with a proactive agency-wide integrated plan to address a pandemic of H5N1[26] and by accelerating many of the initiatives that are contained in Critical Path,[27] 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*[28] 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.[29] 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

24. *See* CHRISTOPHER CUMO, SCIENCE AND TECHNOLOGY IN 20th-CENTURY AMERICAN LIFE 35–52, 101–116, 149 (2007) (discussing the scientific and technological developments in the twentieth century and beyond).

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 gate keeper 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.").

26. U.S. FOOD & DRUG ADMIN., EMERGENCY PREPAREDNESS AND RESPONSE: FDA PANDEMIC INFLUENZA PREPAREDNESS STRATEGIC PLAN (2008), http://www.fda.gov/EmergencyPreparedness/Flu/ucm165686.htm.

27. *See* CRITICAL PATH INITIATIVE, *supra* note 10.

28. OFFICE OF CRITICAL PATH PROGRAMS, U.S. FOOD & DRUG ADMIN., THE SENTINEL INITIATIVE: NATIONAL STRATEGY FOR MONITORING MEDICAL PRODUCT SAFETY 13–17 (2008), *available at* http://www.fda.gov/downloads/Safety/FDAsSentinelInitiative/UCM124701.pdf.

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[30] and biosimilars;[31] however, there is much more on the horizon, including the regulation of complex integrated products that incorporate therapeutic, diagnostic, targeting, and delivery constructs.[32]

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, 639–40 (2005).