

The US Food and Drug Administration:

# A Cornerstone of America's Economic Future



ALLIANCE FOR A  
**STRONGER FDA**

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Dear Policymaker,

*The U.S. Food and Drug Administration: A Cornerstone of America's Economic Future* was prepared by the Alliance for a Stronger FDA to assist policymakers in understanding the FDA's role in the nation's economy. FDA is a pre-eminent public health agency that assures that our food supply is safe and that drugs and medical devices are safe and effective. Its primary mission is to serve and protect the American people. In addition to its public health role, the agency and the industries it regulates have a significant, positive role in our nation's economy and in stimulating economic growth and job creation.

Some of the highlights of the FDA's contribution to the United States and the global economy, which are discussed in greater detail in this paper, are:

- FDA-regulated industries account for nearly 25 percent of consumer spending in the United States<sup>1</sup>
- The bioscience industry, which depends on FDA for regulation of its products, directly employed 1.42 million people in the United States in 2008 and generated an additional 8 million related jobs<sup>2</sup>
- The FDA oversees approximately 167,000 registered domestic food establishments, as well as monitoring an additional 254,000 sites overseas involved in the production and processing of the food Americans eat<sup>3</sup>
- FDA plays a critical role in protecting the United States against agro-terrorism and bio-terrorism.

We hope that you will find the following paper helpful in your consideration of the economic impact of the FDA. If you have any questions, please do not hesitate to contact us.

Sincerely,

**The Executive Committee of the Alliance for a Stronger FDA**

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# **Introduction: A Strong FDA is Essential for Continued Growth of the American Economy**

The U.S. food, biopharmaceutical, medical device and cosmetics industries are global leaders, provide millions of well-paying jobs, and are among the few industries generating a positive trade balance with other countries.

The FDA's mission is to ensure that the products it regulates are safe, effective, and properly made. Notably, the industries that the FDA regulates—unlike industries regulated by other federal agencies—have called for a stronger, more robust regulatory agency.

The industries regulated by the FDA depend upon an agency with strong scientific and regulatory capacity that can provide clear, timely, consistent and reliable science-based guidance. A vibrant, effective regulatory system at the FDA is a key contributor to the viability and success of the FDA-regulated industries — and ultimately to our nation's economic success.

The benefits of an adequately funded FDA include building the confidence of American consumers in the products that the FDA regulates. Safe foods and safe and effective medical products are key components of continuing to achieve longer, healthier lives for Americans, as well as increased productivity and reduced disability.

For example, a well-resourced FDA, with modern scientific tools, serves as an invaluable partner to the discoverers and developers of breakthrough products—drugs, devices and foods—by ensuring their safety and helping to accelerate the rate at which patients and consumers can access life-saving treatments and life-enhancing scientific advances.

## Safe and Effective Medical Products Create Jobs, Save and Improve Lives

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America's life sciences industry improves the economy by providing safe and effective medical products—a key component of longer, healthier lives, increased productivity and reduced disability. But, a fact that sometimes remains overlooked is the direct contribution of these industries to the American job market and economy.

According to a Battelle Memorial Institute Report, in 2008, the biosciences—including all life-sciences activities—employed 1.42 million people in the United States.<sup>4</sup> Importantly, the jobs generated in this industry also tend to be better paying—the average annual wage of these workers was \$77,595 in 2008, over \$32,366 more than the average private-sector annual wage.<sup>5</sup> In addition, this industry, which depends on the FDA for consistent and science-based regulation for its survival, generated eight million related jobs.<sup>6</sup> Biopharmaceutical companies invested \$105,428 per employee in 2000-2007—an average of more than 10 times the amount of R&D per employee spent in other industries.<sup>7</sup>

Like the biopharmaceutical sector, the medical device industry also is an important employer. Medical device manufacturers employed 422,778 workers in 2008.<sup>8</sup> One important aspect of the medical device industry is the large number of small businesses that make up this industry – all of which are job creators. According to Dunn & Bradstreet, the number of medical device

manufacturers in the United States has grown from 10,000 in the late 1990s to more than 20,000 a decade later. Today, 98 percent of medical device manufacturers have fewer than 500 employees, and 71 percent have fewer than 10 employees

Generally, medical technology jobs also tend to be well-paying—for example, in Arizona, Wisconsin and South Dakota, medical technology jobs paid more than 50 percent above average state earnings.<sup>9</sup> The average of the earnings for these types of jobs was below the state average in only seven states.<sup>10</sup>

The rapid technological progress medical technology companies have achieved has had a significant impact on the health of Americans. In research commissioned by the device industry, from 1980 to 2000, rapid technological progress resulted in a 15 percent decline in annual mortality, a 25 percent decline in disability rates, and a 56 percent reduction in hospital days.<sup>11</sup> The small businesses that comprise this industry have had a significant impact directly and indirectly on the economy—adding jobs and securing the health of our nation's workforce through their innovative products.

### **Medical Breakthroughs Significantly Improve Patient Outcomes**

Medical breakthroughs, which depend on a vibrant industry and an adequately funded

FDA, also have a significant economic impact. An important example can be found in the area of Alzheimer's disease. The Alzheimer's Association has determined that a breakthrough that delays the onset of Alzheimer's disease by five years would mean 1.6 million fewer Americans would have Alzheimer's.<sup>12</sup> Further, the United States could save \$50 billion *per year* in medical costs within five years of the approval of such a product and \$111 billion per year within 10 years.<sup>13</sup> The Council for American Medical Innovation reports that most of these savings would be in Medicare and Medicaid spending at a time in which policy makers are searching desperately for ways to lower federal health care spending.<sup>14</sup>

The opportunities are not isolated to one or two specific diseases. The benefit of private and public investment in FDA-approved life science innovations has been repeatedly demonstrated. Yet it is important to remember that none of this can occur without the FDA's ability to provide the most up-to-date science-based reviews for safety and effectiveness.

Societal benefits of life-science innovation can also be determined through economic analysis. According to one economic analysis, every additional \$1 invested in the life sciences in the 1980s subsequently generated societal benefits between \$1.90 and \$2.60.<sup>15</sup> More recently, studies have shown that the potential savings are exponentially higher. For example, one study of Medicare claims data showed that

for patients who suffered a heart attack, every additional dollar spent on statin therapy produced health gains valued as high as \$9.44.<sup>16</sup> Every additional dollar spent on the routine use of beta blockers in patients suffering acute heart attacks produced health gains valued as high as \$38.44.<sup>17</sup>

The societal benefits of the U.S. life sciences industry are not just limited to impacting America. Indeed, U.S. research and development leading to innovative new products is also vital for the world's health. A Columbia University study attributed 40 percent of the two-year gain in life expectancy across 52 countries to new therapies.<sup>18</sup>

The FDA is a critical component to the industries' success because it (1) provides appropriate reviews for safety and effectiveness, and (2) helps provide consumers with confidence that these technologies are safe and effective.

### **Ensuring that U.S. Companies Can Successfully Compete Overseas**

While the United States has been dealt a strong blow by recent economic challenges, new medical products, approved and regulated by the FDA, are likely to play a significant role in helping our economy regain its footing.

The United States also leads the world in R&D spending. "In 1990, the pharmaceutical industry spent 50 percent more on research in Europe than in the

United States In 2001, the situation was reversed with 40 percent more spent in the United States.”<sup>19</sup> The money spent on R&D drives the economy in both direct job-creation in the life sciences industries and spending on ancillary products and services to supply research.

The United States is a dominant player in the global pharmaceutical market, as well. The pharmaceutical output of New Jersey alone—all of which is approved and regulated by the FDA—surpasses that of Australia and the Middle East combined, and nearly matches the output of Asia.<sup>20</sup> Device exports are also growing rapidly—from \$28.3 billion in 2007 to \$36 billion in 2009.<sup>21</sup>

Assurances as to the expeditious approval of safe and effective new products have been a key driver in the success of the medical product industries. Over the last four years, the FDA has hired new medical officers, pharmacologists, statisticians, and other key personnel to provide expedited reviews of applications for medical products.

This has resulted in a drop in overall approval times for new drugs from a median of 13.2 months in 1993 to less than a year today,<sup>22</sup> meaning earlier access for patients to life-saving therapies and a faster return on investment for pharmaceutical R&D (thus freeing investment funds for new R&D). As a result, about 1,010 new drugs and about 100 biologics have been approved, including 62 new cancer drugs, and even larger numbers for endocrine, psychiatric, and cardiovascular conditions, as well as 96 new anti-infective drugs.<sup>23</sup>

However, the companies that develop medical products face tough challenges in the global economy. An effective regulatory environment that helps to foster consumer confidence and facilitate the growth of FDA-regulated industries is critical.

Also at issue is the rapidly growing international competition, particularly from Europe and China. Other countries are investing billions in a concerted effort to leapfrog the United States in the medical products industries. For example, six years ago, the FDA announced the Critical Path Initiative (CPI) to provide the agency with the tools and knowledge to advance innovation in areas regulated by the FDA. Support from all sources has been modest (less than \$100 million).<sup>24</sup>

In contrast, in 2007, the European community announced its Innovative Medicine Initiative Joint Undertaking (IMI-JU). Public and private commitments to the IMI-JU exceed more than \$1 billion.<sup>25</sup> European governments view these types of initiatives as the key to sparking innovation and accelerating their own economic development.

One of the main goals of the IMI-JU is to overcome bottlenecks in the development of innovative medicines. In particular, this effort focuses on better methods for predicting safety and efficacy for potential medicines in therapeutic areas, such as brain disorders, infectious diseases and cancers. One of its goals is to reverse European “brain drain” (i.e., the flight of European scientists to the United States) and enhance

European competitiveness. China is expected to match the European investment in drug development research.<sup>26</sup>

While patients benefit from treatments, regardless of country of origin, the economic benefits of a successful medical product go largely to the innovating country.

The potential costs to the American economy of losing our competitive edge are enormous. The United States lead in drug development that emerged in the 1990s is associated with the increased rapidity with which the FDA reviewed new drug applications for safety and efficacy the and increased consultation with drug developers. Many leaders in the pharmaceutical industry believe that the determined efforts of Europe and China can only be deflected if the FDA is given the resources to provide the guidance that medical products companies need. Billions of dollars and millions of American jobs depend upon those endeavors.

### **Reducing Healthcare Costs**

In addition to its role in innovation, one of the FDA's most important contributions is its capability relating to reducing health care costs. Low-cost generic drugs are a prime

example. The availability of generic drugs saved the health care system \$140 billion last year alone and almost a trillion dollars over the past decade. Yet due to funding constraints, there is a growing two-year backlog of generic drug applications at the FDA, which threatens to dramatically reduce those savings in future years. This backlog potentially costs payers, including the federal government, and patients billions of dollars every year.

Health economists recognize that pharmaceutical therapies are critical to holding down health care costs, as these interventions can prevent or treat illness and help avoid more costly medical problems. Notably, Americans spent about \$234 billion on medications in 2008 – comprising 10 percent of national health care spending (as compared with 31 percent for hospitals and 21 percent for physician services).<sup>27</sup>

The FDA needs adequate resources to continue to ensure that biopharmaceutical, medical device and vaccine applications are reviewed for safety and efficacy in a timely manner. Societal savings from life science innovation can be enormous-but it cannot be achieved without recognizing the FDA's central role.

## **Food Industry: Securing a Safe, Abundant, and Varied Food Supply**

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The FDA is responsible for the safety of approximately 80 percent of the U.S. food supply. (The Department of Agriculture is

responsible for the remaining 20 percent). The U.S. food supply, by any objective measure, is probably the safest, most

abundant, and most varied of any in world history. This vital FDA-regulated industry, which contributes \$1.165 trillion<sup>28</sup> (about 8 percent) to the U.S. GDP, feeds not only the United States, but also much of the entire world.

The scale and scope of the FDA's tasks in this area are daunting. The FDA is responsible for overseeing the food that will be served at one million U.S. restaurants and in over 100 million American kitchens. That food comes from two million U.S. farms and many millions of tons of food imported into the United States.<sup>29</sup> The FDA is also responsible for overseeing approximately 167,000 registered domestic food establishments as well as monitoring an additional 254,000 sites overseas, involved in the production and processing of food Americans eat.<sup>30</sup>

The FDA's oversight can be found on every continent, and in nearly 100 different countries—working to ensure that the food Americans eat is safe to consume. An adequately funded FDA therefore allows the United States to serve as the world's breadbasket and enables Americans to enjoy the culinary and cultural diversity that the global market has to offer.<sup>31</sup> As an example of the progress in this area—most Americans have forgotten the time when canned fruit was the only readily available option in winter. Thanks in part to food imports, Americans have a plentiful supply of fresh fruits year-round.

## The Growing U.S. Export Market

One of the brightest spots in the U.S. industrial landscape has been the growing export market for food products. While the United States has long been a net exporter of raw foods, such as wheat and corn, foreign countries are increasingly importing U.S. “finished” foods, such as snacks, frozen foods, and other products. The U.S. processed food industry is a major participant in the global economy—in 2008, the U.S. processed food industry exported \$48.5 billion of product (marked growth when compared with about \$25 billion 10 years earlier).<sup>32</sup> The processed foods industry employs about 1.5 million people.<sup>33</sup>

However, this growth is placed at risk when the FDA does not have the resources to rapidly track, identify, and stop the outbreak of foodborne diseases. For example, following the 2006 *E. Coli* in spinach outbreak, the Mexican government announced its intention to consider banning importation of U.S. produce into Mexico. The robustness of FDA's efforts has a direct impact on the economic viability of American food exports.

Another responsibility of the FDA is the regulation and inspection of imported food. Each year, the average American eats about 260 pounds of imported foods—13 percent of the annual diet—yet less than 2 percent will be examined by an FDA inspector.<sup>34</sup> Coupled with imported pharmaceuticals, medical devices, animal feed and other FDA-regulated products, the resources

available for the FDA to inspect products are insufficient.

New data from the CDC finds that one in six Americans get sick each year from foodborne causes.<sup>35</sup> Of those, 128,000 will be hospitalized and 3,000 will die each year.<sup>36</sup> The resulting economic effects are huge. Another estimate puts the societal and health costs of foodborne illness at \$152 billion annually.<sup>37</sup> Needless to say, taxpayers shoulder the burden of these costs, in part through lost productivity, but also through Medicare and Medicaid program spending. All of this could be significantly diminished if the FDA had the resources

necessary to implement a more robust food safety and inspections system.

Also important, and troubling, are the economic losses to farmers and food producers, from recurrent outbreaks of foodborne disease. For example, the *E. Coli* outbreak in spinach in 2006 cost spinach producers an estimated \$100 to \$200 million;<sup>38</sup> the 2008 *Salmonella* Saintpaul outbreak in tomatoes and peppers resulted in producer losses of \$450 million;<sup>39</sup> the *Salmonella* Typhimurium outbreak in peanut butter cost growers about a billion dollars in 2009;<sup>40</sup> and the 2010 egg outbreak from *Salmonella* resulted in losses associated with the recall of half a billion eggs.<sup>41</sup>

## Protecting Society from Terrorist Threats and Naturally-Occurring Emerging Infectious Diseases

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The FDA has helped protect us against other kinds of diseases as well. We have been subjected to one biological attack thus far – the anthrax scares of 2001 that left five dead and an additional 17 infected. But, the threat of another attack remains very real. Smallpox, Ebola hemorrhagic fever, and botulinum are additional threats, all of which are deadly and believed to be capable of weaponization by terrorists. In addition, natural threats, such as pandemic influenza, remain worrisome to public health experts.

The CDC estimates the economic impact of a bioterrorism attack could reach \$26.2 billion per 100,000 people exposed.<sup>42</sup> In a city like New York, with a population of

about 8.4 million,<sup>43</sup> widespread exposure to bioterror agents could cost over \$2 trillion. For comparison, the estimated cost of the September 11<sup>th</sup> attacks was \$83 billion, nearly 25 times smaller than the potential costs of a bioterror threat.<sup>44</sup>

Naturally-occurring threats can also be costly. In 2008, the World Bank estimated that a flu pandemic could cost \$3 trillion worldwide, accompanied by more than 70 million deaths and a nearly 5 percent decrease in world GDP.<sup>45</sup> WBB Securities, LLC released a report predicting \$488 billion lost in the United States during the first year following a flu pandemic, with a

permanent economic loss totaling \$1.4 trillion.<sup>46</sup>

Humans aren't the only potential target. Responsibility for combating agro-terrorism is shared between the FDA and the U.S. Department of Agriculture. The FDA is responsible for animal drugs, animal feed, and "field to table" for non-animal agricultural products.

Radford G. Davis, Assistant Professor of Public Health at Iowa State University, estimates that a terrorist-induced outbreak of Foot and Mouth Disease among cattle in the United States could cost the nation \$27 billion annually *in trade losses alone*.<sup>47</sup> Dr. Frederick Murphy, Dean of the School of Veterinary Medicine at the University of California Davis, reports global losses as high as \$50 billion and as many as 300,000 jobs put at risk after the mad cow scare of 2000.<sup>48</sup>

Agricultural bioterrorism, if successfully carried out, could also severely undermine confidence in the security of the food supply. As Dr. Davis put it: "Add to this the costs of depopulating infected herds, disinfecting premises, quarantines, surveillance, higher prices of meat, it all adds up to a heavy price."<sup>49</sup>

The FDA's crucial role in regard to these potential threats was recently highlighted in the Department of Health and Human Services' August 2010 review of Emergency

Medical Countermeasures (MCMs). The report describes that "[t]he FDA [as] critical to the success of the enterprise, as it oversees, from a regulatory standpoint, the entire evaluation process of MCMs [medical countermeasures], including emergency use authorizations (EUAs) and post-marketing surveillance for safety and appropriate use."<sup>50</sup> Furthermore, the report states that "enabling innovative regulatory oversight by the FDA is an essential step in transforming the MCM enterprise."<sup>51</sup> The report further highlights the importance of applied regulatory research performed at the FDA in collaboration with other governmental and non-governmental partners.<sup>52</sup> According to the report, the FDA needs "a strong, expert scientific workforce and infrastructure" to support this type of innovation.

The FDA has also stepped into a larger role as a key agency in the war against biotreats, whether natural or man-made.

Key FDA responsibilities in this regard include registering foreign and domestic food suppliers, fostering the development of vaccines, drugs and diagnostic products to help respond to bioterrorist threats, serving on an interagency workgroup responsible for preparing our nation for a civilian emergency, and participating in setting a federal research agenda for bioterrorism preparedness. All of these crucial efforts by the FDA help keep our nation safe against the possible threat of biological attack.

## Conclusion

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The promise of the life sciences and the high-tech food and agribusiness sectors—economic expansion, jobs, and new therapies and products for unmet needs—requires an adequately funded FDA and a strong, reliable regulatory environment. As the FDA’s Commissioner Margaret Hamburg has noted, the FDA’s regulatory science—the tools and knowledge to make efficient, effective and correct regulatory decisions—has become weak and underdeveloped, a trend that threatens the growth and success of the American life sciences and food sectors. This is creating roadblocks between basic/translational research and successful development of new drugs and devices and safer foods.

The FDA plays a critical role in the U.S. economy. This will not change and is certain to become even more important over the next decade.

An adequately funded FDA has the potential to be an extraordinary catalyst for the American economy. With appropriate funding, the FDA can continue to help drive American innovation and increase the country’s competitiveness in the global marketplace, while also serving the public health needs of the American people.

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