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Greg Simon

FDA REFORM: THE WHITE HOUSE VIEW

GREG SIMON*

During a previous speech, I was asked to speak about technology in the future and address the question, "What does the future hold for society?" To exemplify the challenges of how we will use our technology, and the type of society we will have, I chose the emerging science of genetic engineering and its relationship to the many changes taking place in the digital and computing world. For example, our understanding of digital processes has enabled us to further understand the genetic code and the way it works. At the same time, the knowledge we gain from biotechnology helps us to understand computers and how to actually grow programs, instead of merely writing them. We are now able to evolve algorithms inside a computer and take the process of DNA and put some of that knowledge into a computer and learn things that we then apply to our studies in biotechnology.

Although we have a long history of thinking of biotechnology as being alienated with specialized vocabularies, it is important to remember that every

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* Greg Simon is the Chief Domestic Policy Advisory to Vice President Al Gore. During the 1992 presidential campaign, Mr. Simon was Issues Director for Vice President Gore. He joined Vice President Gore's staff as Legislative Director in March 1991, when the Vice President served in the Senate. Before joining Gore's Senate staff, Mr. Simon served as Staff Director of the Subcommittee on Investigations and Oversight of the House of Representatives' Science, Space and Technology Committee, which he joined as counsel in 1985.

In his current position, Mr. Simon is the Vice President's top advisor on economic and science and technology issues, including telecommunications, space policy, and biotechnology. In that capacity, he represents the Vice President in such policy making bodies as the National Economic Council, the Domestic Policy Council, the Office of Science and Technology Policy, and numerous interagency task forces. During his years with the Science Committee, he organized a series of investigatory hearings on biotechnology policy and was involved in hearings and investigations related to NASA, scientific misconduct, neurotoxins, the use of human biological materials in research and the artificial heart program.

In December 1989, Mr. Simon received a European Community Visitors Program Fellowship to visit the EC Commission in Brussels, the European Parliament in Strasbourg and government officials in London, Rome and Madrid with a focus on biotechnology and space programs.

His many invited presentations include an appearance as the inaugural speaker in the Shidler, McBroom, Lucas & Gates Lectureship in Law and Technology; addresses before the National Academy of Sciences Committee on Science, Engineering and Public Policy; the Academy's panel on Scientific Responsibility and the Conduct of Research; the Center for Clinical Medical Ethics at the University of Chicago; and the Pew Science Program symposium on Undergraduate Science Education for the 20th Century. He was also recently an invited participant in conferences sponsored by the Biotechnology Industry Organization and the Competitive Telecommunications Association.

Mr. Simon received his law degree form the University of Washington in 1983. He was a member of the Washington Law Review and the Moot Court Board and was voted Outstanding Oralist of the 1983 Northwest Round of the Jessup International Law competition. He is a member of the Washington State Bar and practiced for two years at the firm of Roberts and Shefelman in Seattle in commercial litigation and intellectual property.

A native of Arkansas, Mr. Simon attended the University of Arkansas where he was awarded a B.A. in History, *summa cum laude*, in 1973. He attended the University of Vienna in Austria from 1971-1972, studying European diplomatic history in the period between World War I and World War II.

aspect of biotechnology has countless implications in many other areas of life. As biotechnology raises various questions, especially ethical questions, it is important for us to keep our social vision ahead of our technological problems. Our decisions about where we as a society wish to go must be as modern and fresh as our developing technology.

The biotechnology industry has a long history of addressing these questions head-on, and the topic of FDA reform is a very good nexus point for discussing how we integrate new technologies with old concerns. In the case of the FDA, the age-old concern is that the products we give to the people, what we put out on the street, should be safe, efficacious, and of high quality. Biotechnology presents a lot of challenges to the regulatory system. The Clinton administration has tried to address those challenges through many of the reforms that we have already put into place through our Reinventing Government initiative.[1]

Last November, the FDA, with Vice President Gore and President Clinton, announced new measures to reduce costs for the manufacturers of biotechnology-derived pharmaceuticals to shorten the drug development time and reduce paperwork.[2] These measures eliminated the need for approval of promotional labeling before launching a new product.[3] The FDA also committed to review and respond within thirty days to information that is responsive to a clinical hold on an investigational[4] drug or biologic.[5] We eliminated the necessity of an establishment license application for well-characterized therapeutic biotechnology drugs.[6] We also eliminated the FDA's lot-by-lot release for well-characterized therapeutic biologic drugs that

1. Remarks Announcing the Report of National Performance Review and Exchange With Reporters, 29 WKLY. COMP. PRES. DOC. 1700 (Sept. 7, 1993).

2. The measures were announced in the Indian Treaty Room, Old Executive Office Building, on November 9, 1995. Also present were FDA Commissioner David Kessler and Health and Human Services Secretary Donna Shalala.

3. *See* Food and Drug Inst., *Reinventing the Regulation of Drugs Made from Biotechnology*, 7 FOOD AND DRUG REP. 252 (1996).

4. An investigational drug is one which an Investigational New Drug (IND) application has been filed with the FDA. The application provides the FDA with information on drug composition, manufacturing data, data on experimental controls, results from laboratory and animal testing, intended procedures for obtaining consent of subjects and protecting their rights and an overall plan for human clinical studies. U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY 249 (1991).

5. Biologics are vaccines, therapeutic serums, toxoids, antitoxins, and analogous biological products used to induce immunity to infectious diseases or harmful substances of biological origin. *Id. at 268.*

6. "Well-characterized" therapeutic biotechnology drugs are therapeutic products whose "identity, purity, impurities, potency and quality can be determined and controlled." Steve Sterberg, *Three Days of Debate Yields Possible Consensus on FDA Definition for Biotech Products*, Bioworld Today, Dec. 14, 1995, *available in* LEXIS, NEXIS Library, Magazine file. Most biotech drugs are in this category.

are licensed for marketing.[7] We consolidated twenty-one different forms into a single format[8] and allowed biological drug manufacturers to get licenses for pilot facilities without building full-scale manufacturing plants.

Last March, President Clinton and the FDA announced four new initiatives to improve patient access to new cancer therapies:

(1) speeding up the approval process by using tumor shrinkage as a surrogate marker;
(2) expanding patient access to experimental cancer drugs approved in other countries;
(3) increasing patient representation on cancer drug advisory committees;
(4) and making it easier for sponsors to test new uses for cancer therapies already on the market.[9]

The driving force behind FDA reform now is the medical device industry and the progress it has made. In the fiscal year 1995, 98% of the medical device reviews were completed within 138 days. In the fiscal year 1994, 5,498

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7. The lot-by-lot requirements are the result of a traditional distinction made between biological and non-biological drugs. "Historically, biological drugs–blood and blood products, vaccines, extracts of natural substances for treating allergies, extracts of living cells and the like–were treated differently from other drugs because they were often rather impure and the active substances poorly characterized." Henry I. Miller, *FDA is Performing Magic with "Biological" Drugs*, WASH. TIMES, Nov. 15, 1995, at A15.

Carl Feldbaum, president of the Biotechnology Industry Organization, "noted that the laws governing biotechs date back to 1912, when Congress cracked down on unscrupulous entrepreneurs selling horse blood and other bodily fluids as treatments for diseases [such as] diphtheria." Zachary Coile, *Biotech Unbound: Industry Welcomes Overhaul of Drug Approval Process*, S.F. EXAMINER, Nov. 27, 1995, at D1.

These characteristics of biological drugs led the FDA to establish the lot-by-lot requirements for biologics:

> [Since] it was difficult to demonstrate that each batch met specified standards of purity or potency, the FDA required that the product's sponsor demonstrate a high level of control over the manufacturing process–every procedure had to be done in a highly regimented and reproducible way. The regulators granted approval of the product itself, which had to be safe and effective, and also of the manufacturing establishment, certifying that there was adequate control and rigor in production. In addition, samples from every production batch had to be submitted for certification by the FDA, which analyzed them for purity and potency (to the extent it was possible).

Henry I. Miller, *FDA is Performing Magic with "Biological" Drugs*, WASH. TIMES, Nov. 15, 1995, at A15.

Non-biological drugs have had no lot-by-lot requirements. The reforms eliminating such requirements for biologics will harmonize the approval processes for biological and non-biological drugs.

8. FDA Form 3439, Interim Form for Application to Market a New Drug, Biologic, or Antibiotic Drug for Human Use, 61 Fed. Reg. 24,313 (1996). The format was not released at the time these measures were released. The proposed revised format was expected within six months from November 1995.

9. President's Remarks on the Anticancer Initiative, 32 WKLY. COMP. PRES. DOC. 587 (Mar. 29, 1996).

reviews were completed in 182 days. In one year, the FDA went from approximately 5,500 reviews taking 182 days to roughly 5,600 reviews taking 138 days or less.

Considering the volume of devices involved here, and their impact on our health care system, an increase of 25% in one year for 98% of medical devices is a significant improvement. To further this improvement, we developed a pilot program to review low to moderate risk medical devices by outside organizations and expanded 125 categories of low-risk medical devices exempt from pre-market review.

In terms of FDA drug approvals in 1995, 82 new drugs were approved in 16½ months (median) compared with 62 new drugs approved in 19 months the year before. Twenty-eight of the 1995 approvals were for entirely new drugs, not new formulations of existing drugs. Fifteen of the 1995 approvals were priority drugs[10] and were approved in 6 months, compared with 17 priority drugs approved in 15 months the year before. In October of 1995, the General Accounting Office (GAO) reported that the FDA approval times for priority drugs were shorter in the United States than they were in the United Kingdom and that the median approval time for new drugs in calendar year 1994-1995 in the United States was the same as that in Britain and faster than that in France, Spain, Germany, Australia, Japan, Italy, and Canada.[11] Yet progress is not the end of the story—it is merely the beginning. The question now is, "Where does FDA reform go from here?"

It is important to first summarize the goals of FDA reform. There are many ways to reform, but we have always first supported reform that builds on the progress we have already made in expediting the review of drugs, therapeutics, and devices as quickly as possible while meeting the standards that the FDA is charged by law to meet. The American public has a right to expeditious pharmaceutical approvals, while being confident in the safety and efficacy of the drugs, devices, and therapeutics that come on to the market.

Reform should not be dismantled; neither should it choke someone to death. Therefore, we have asked for the types of resources that the FDA needs to get the job done. Everybody knows that the improvement in pharmaceutical reviews came about because of the Drug Fee User Act[12]: the ability to channel industry resources to the FDA, which is then more able to efficiently and speedily review new drugs and therapeutics with greater resources. The industry once supported a device user fee, but such support has recently disappeared. Thus, the question arises, if we do not put more resources into device review at the FDA, how can we reform it? What can

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10. "A priority drug is one that the FDA determines to represent a significant therapeutic advance either offering important therapeutic gains (such as the first treatment for a condition) or reducing adverse reactions." GAO REPORT: FDA DRUG APPROVAL–REVIEW TIME HAS DECREASED IN RECENT YEARS, at 37 (1995) [hereinafter GAO Report].

11. *Id.* at 80-81.

12. Prescription Drug Establishment, and Prescription Drug Product Fees, Pub. L. No. 102-571 § 106, Stat. 4491 (1992) (codified at 21 U.S.C. § 301).

we do to address the concerns that the biotechnology industry has about the review of biotechnology products?

First, we fully support legislating any of the reforms that we have put in place through the Reinventing Government initiative. We were able to implement most of the Reinventing Government initiative reforms administratively,[13] but people who worry about the vacillation from one administration to the next prefer that these reforms be in statutory language. This is not really a problem—these reforms will continue for everyone over whom we have the executive power of implementation.[14]

I point out also that the exportation of unapproved drugs was approved and increased in the recent budget in a way we support. The FDA did this by expanding the philosophy that before a drug which has not yet been approved in the United States can be exported, it must be approved by both the importing country and another country that has a recognized system of pharmaceutical review with certain standards they were forced to meet.[15] Those countries had been listed in statute[16] for a long time. The bill allows expedited export if one of those listed countries has approved it and it has been approved by the importing country, though there are some exceptions and waivers that add to that.[17]

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13. Some representative regulations changes in this reform are: 21 C.F.R. pts. 600, 601, 620, 630, 640, 650, 660, 680, 801, 862, 866, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892 (1996).

14. There is a problem in implementation. Even with the best of staffs, how do you go from the rules to the implementation? As Truman said when Eisenhower was elected, "I can't wait for this general to come into the Oval Office, pick up the phone, bark an order and put it down and nothing happens." That is what happens in a large bureaucracy. We have a large bureaucracy because we have a large country, and we have a lot of things to do, especially at the FDA. I am amazed at the volume of work the FDA has. We are fighting very hard to send the message down the chain in terms of the attitude we expect from professionals and the kind of customer service we expect. We have made a lot of progress, but we still have a long way to go.

15. 21 U.S.C. § 382(b)(1) (1996) (amending 21 U.S.C. § 382(b)(1) (1994)). This section was amended April 26, 1996.

16. 21 U.S.C. § 382(b)(1) (1994), *amended by* 21 U.S.C. § 382(b)(1) (1996). The previous version of the statute specified approved countries for drug exportation. Those countries were Australia, Austria, Belgium, Canada, Denmark, Federal Republic of Germany, Finland, France, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

17. The current version of the statute provides for exportation if the drug or device complies with the laws of that country to which the drug or device is being exported and if the drug or device has been approved by Australia, Canada, Israel, Japan, New Zealand, Switzerland, South America or in the European Union or European Economic Area. Unlike the prior version, the current version provides for direct importation if the criterion are met and does not require an application and approval process. However, the exporter must notify the FDA when it first begins importation and must maintain records of the drugs/devices and the countries to which they were exported.

Exceptions and waivers include the following:

1. A drug or device intended for investigational use in any listed country may be exported in accordance with the laws of the country and are exempt from regulation. 21 U.S.C. § 382(c) (1996).

We support the current legislative debate reforms that would incorporate performance standard approaches to the way that drugs and devices are reviewed: expediting the marketing of drugs and devices for serious conditions; contracting-out of FDA inspections that occur; reduction and, in some cases, elimination of environmental impact statement requirements in areas where there has never been any environmental impact noted or even suspected; and exempting many of the less dangerous devices from pre-market review by the FDA.[18]

What we have opposed in Senator Kassenbaum's (R-KS) legislation,[19] and what we are currently negotiating with many members of the Congress, is the idea that we utilize quick review as a trigger for contracting-out or other changes in the way we review drugs intended for the marketplace. In the vernacular, this is referred to as "the hammer." The hammer works as follows: If the FDA does not review a certain percent of drugs within a certain amount of time, they are forced to contract-out and have someone else do it. One problem with the hammer is that many of those review times are less than the times that are listed in the Drug Fee User Act,[20] which was a compromise reached between the government and the industry.

Another problem is the concept that you would punish a regulatory agency for not meeting a statutory deadline and contracting-out when you are not providing the resources necessary to meet those deadlines. Everybody

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2. A drug or device intended for formulation, filling, packaging, labeling or further processing the anticipation of market authorization in any listed country may be exported for use in accordance with the laws of that country. 21 U.S.C. § 382(d) (1996).

3. Exportation of a drug or device used in the diagnosis, prevention or treatment of a disease which is not prevalent in the United States requires prior approval. 21 U.S.C. § 382(e) (1996).

4. A drug or device may not be exported if the drug or device:
(a) is not manufactured, processed, packaged and held in substantial conformity with current good manufacturing practice requirements; or
(b) does not meet international standards; or
(c) is adulterated; or
(d) is likely to be re-imported; or
(e) presents an imminent hazard to the people of the country to which is it being exported; or
(f) is not properly labeled.

21 U.S.C. § 382(f) (1996).

5. In any event though, the FDA will notify the country to which the drug is being exported if an application for new drug (21 U.S.C. § 355), pre-market approval (21 U.S.C. § 360(e)), or for exportation of partially processed biologic products (42 U.S.C. § 262) was disproved. 21 U.S.C. § 382(a)(2)(2) (1996).

18. S. 1477, 104th Cong., 1st Sess. (1995).

19. *Id.*

20. Approval times vary, depending on the type of drug or device: 180 days for new drugs (21 U.S.C. § 355), new animal drugs (21 U.S.C. § 360(c)), and pre-market approval for Class III devices (U.S.C. § 360e(d); 120 days for product development protocol (21 U.S.C. § 360d(f)); and 90 days for intended use of animal fee containing new animal drug (21 U.S.C. § 360b(m)).

knows that there is a mismatch between the demand and the resources. This is not just unfair in general, but it is a dangerous way to do business.[21] The concept of contracting-out for private review of therapeutics and drugs devised for public consumption raises a question: If people are so willing to pay a third party to do it, why aren't they willing to pay the FDA to do it? This is certainly the case with regard to devices. If people are willing to pay a third party to review a device, why aren't they willing to set up a user fee system to have the government do it? At this time, we are not proposing a user fee for devices because that debate is over; however, we are proposing to remove the "hammers" from the bill and talk about real ways to improve the long-term health of the review process. The long-term health is not served by looking at what happens during the next six months and then what happens during the six months after that.

We do not believe that if a foreign government approves a drug, that drug should automatically go to the head of the line in the United States. That is a dangerous way to organize our priorities. Our priorities ought to be the health and safety of the drugs that are provided to the American public. If other countries with smaller populations and smaller government burdens are able to review some drugs more quickly than others, that is terrific for those companies; but our priorities should be those which we set, not those dictated by foreign governments. We have a difficult time with the idea that we should force our decisions based on what other people are doing.[22]

We also have concerns over eliminating all the requirements to notify the FDA of certain changes to manufacturing processes.[23] As Yogi Berra once said, "It's not the things you don't know that get you in trouble, it's the things you know for sure that just ain't so." When people are certain that

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21. This raises a troubling point about the experience of reviewers. It is very difficult, especially in the current environment, to get people to stay in public service when they can have such lucrative careers in the biotechnology or the pharmaceutical industries. If they stay in the public service, they get beaten up every day in the Congress; they get blasted in the press; good work is seldom noted in public. It is simply not a glorified place to work. It has a lot of meaning, and there are a lot of devoted people who will be there for years and years, but until we give the professionals in the government the kind of compensation and respect that they deserve, we will constantly have people seeking better opportunities in the private industry.

22. This is not to say that we are not actively pursuing harmonization and the expedited approval that comes with harmonization of data. The difficulty is that the House bill requires a drug to go to the top of the line at the FDA if it has been approved by another country. Requiring the FDA to suddenly stop what it is doing based on its priorities and take a drug and review it within a certain time frame after its approval in another country is a different question. We totally support the ability to expedite approval through the harmonization of data. In addition to that, the approval of a drug in another country does have an impact on our export rules, under the new changes that were recently made. Harmonization is the goal, but to move something to the top of the list because it has been approved in another country really steps into the decision at the FDA about what constitutes a priority. This is a decision that we should not leave to other countries.

23. Currently, each application for a new drug requires a full description of the manufacturing process. 21 U.S.C. § 355(b)(1)(D) (1994). Any change to an approved application requires notice to the FDA, either through a supplemental application or in the annual report to the application. Furthermore, FDA approval of the supplemental application is required before any changes can be made. 21 C.F.R. § 314.70 (1996).

their change is safe, that is exactly the time when they should get a second opinion. Of course, companies do not get a second opinion for every change they make. We have proposed certain guidelines about the kinds of changes that need to be reviewed—but the concept that we can expand the exemption of pre-market review of certain changes in manufacturing ignores the history of changes both in the vaccine area and in the device area. These changes have had significant impacts on human health or might have, had the FDA not reviewed them.

The topic of off-label uses is very complicated and affects the biotechnology industry directly, but is not currently in the Senate bill. There is a balance of interests here that requires a lot of thought on both sides. There is an argument that goes as follows: If a respected journal publishes a trial that shows a use for an improved product not currently on its label, and that information is helpful in the practice of medicine, the information should be widely disseminated. This argument has a lot of surface appeal, and the law does not prevent a doctor from finding out about those uses. It does, however, prevent people from publishing those uses to a mass audience as a way of advertising or otherwise disseminating information about an off-label use.[24]

From the government's perspective as the guardian of public health, the concern is that the dissemination of off-label uses becomes a back-door way to approving other uses for a drug that may have been too difficult to get approval for initially. A company gets the drug approved for its easiest use. It then uses a study or two published in a journal to market it in the practice of medicine for other uses and never submits that information to the FDA.

The other concern is that there are often situations in which suggested uses for approved drugs and devices prove beneficial in one study, but competing studies show the opposite. There is no obligation for a company to disseminate all the studies conducted. This argument may not be resolved—both sides have very good cases. Both sides have important interests involved and we are hoping to reach an agreement directly with the industry and the FDA. Another alternative is to legislate an off-label policy that encourages people to submit the new data and efficacy supplements to the FDA. In exchange for this data, they would be able to distribute the information from certain prestigious journals to practitioners of medicine.

The legislation pending on the Hill is very different in both tone and extent. The House has broken up the legislation into several different

24. An advertisement for a prescription drug covered by a new drug application shall not recommend or suggest any use that is not in the labeling accepted in such approved drug application or supplement. 21 C.F.R. § 202.1(e)(4) (1996).

pieces,[25] unlike the Senate has the Kassenbaum bill, which is supported by a number of prominent Democrats with whom we are currently consulting.

I would like to give you a bright-line example that demonstrates the point about why we think FDA reform is important, but also serious enough that we want to do it right if we are going to do it at all. This bright-line example is the area of third party review of medical devices.

The Clinton Administration proposed a pilot project for third party review of medical devices.[26] The Kassenbaum bill initially had a very similar pilot project that did not include Category Three devices.[27] Senator Wellstone (D-MN), who is very interested in this issue, did not include Class Three medical devices in his earlier legislation.[28] In the Senate committee mark up, Senator Coats (R-IN) offered an amendment to include Category Three devices, and the amendment passed.[29] This is an area where a compromise

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25. 1. The FDA Modernization Act of 1995 was introduced June 6, 1995 by Rep. Ron Wyden (D-OR). The purpose of the bill is to revise the drug approval process and for other purposes. H.R. 1742, 104th Cong. 1st Sess. (1995).

2. The Life Extending and Life Saving Device Act of 1995 was introduced September 8, 1995 by Rep. Jon D. Fox (R-PA). The purpose of the bill is to amend the medical device provisions of the Federal Food, Drug, and Cosmetic Act. H.R. 2290, 104th Cong. 1st Sess. (1995).

3. The Medical Device Reform Act of 1996 was introduced March 29, 1996 by Rep. Joe L. Barton (R-TX). The purpose of the bill is to facilitate development, clearance, and use of medical devices to maintain and improve public health and quality of life. H.R. 3201, 104th Cong. 2d Sess. (1996).

26. On April 6, 1995, the Clinton Administration announced a two-year pilot program to determine if third party review of low to moderate risk medical devices could speed up review. The FDA announced implementation of such a program where the third party would make recommendations to the FDA, but the FDA still makes the final determination. 60 C.F.R. 28617 (1996).

27. Category Three devices are Class III Devices as defined in 21 U.S.C. § 360c (1994). Class III devices are devices intended for human use, and which require pre-market approval.

Class I devices (general controls) are devices which the controls indicated in sections 351, 352, 360, 360(f), 360(h), 360(i), 360(j) are sufficient to provide reasonable assurance that the device is safe and effective. These devices are not used in supporting or sustaining human life and do not present a potential unreasonable risk of injury or illness. 21 U.S.C. § 360c(a)(1)(A) (1994).

Class II devices (special controls) are devices which cannot be classified as Class I because the controls are insufficient to determine safety or effectiveness, but for which there is sufficient information to establish "special controls" to provide such assurance. Such "special controls" include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (for submission of clinical data), and recommendations necessary to assure safety and effectiveness of the devices, especially devices used in supporting or sustaining human life. 21 U.S.C. § 360c(a)(1)(B) (1994).

Class III devices (pre-market approval) are devices which (1) cannot be classified as Class I or Class II because of insufficient available information, and (2) are to be used in supporting or sustaining human life or in preventing impairment of human health, or which present unreasonable risk of injury or illness. Class III devices are subject to premarket approval to provide reasonable assurance of its safety and effectiveness. 21 U.S.C. § 360(c)(a)(1)(C) (1994).

28. S. 1369, 104th Cong., 1st Sess. (1995). This bill was introduced on October 31, 1995 and sent to the Senate Labor and Human Resources Committee that same day. No further action has been taken on that bill at the time of publication.

29. Senator Coats offered an amendment to S.1477 in the Senate Labor and Human Resources Committee. The Committee approved the amendment by a vote of 11-4 on March 28, 1996. S. REP. NO. 284, 104th Cong., 2d Sess. (1996).

is possible and necessary. We do not think that you save either resources or time by contracting-out to private parties who would be paid by the company seeking approval for devices that are so serious that any deficiency in the review could lead to the loss of a single life. It will not save either time or money because the FDA would review the review.

When you are dealing with a life-saving device, to review the review is basically to do the review again. There is no such thing as just checking the bottom line to see if it looks good. This is not a case of a "performance" standard that one can meet with some objective criteria. This is a case of the efficacy standard and whether something has a proper impact on saving or prolonging human lives.[30]

So, what is a possible compromise? We have proposed that if you want to save resources that can be applied to Class Three devices within the FDA, you should limit the pilot project to Class One and Class Two.[31] We would like to expand the Class Two definition to include devices that can be reviewed based on safety and performance. Category Three would be comprised strictly of devices that need to be reviewed for safety and efficacy. By using or contracting-out the resources to review Class Two, where there is a performance standard to meet, you free up resources that the FDA can apply to Class Three without having to do the review twice to ensure that serious medical devices are not going into the market without a thorough, objective review by a disinterested party.

I refer to this as a bright-line test about the kind of reform we ought to have. We can have reform that accomplishes both industry and government goals with some of these compromises: on-label and off-label uses; the contracting-out of medical devices; manufacturing changes; and pre-market notification. These changes, taken in conjunction with the changes that we announced in the Reinventing Government initiative, can make a reform package that has meaning, and which can be passed this year.

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30. The logical question at this point is, "If some of these reforms come about, what happens with regard to the liability issue if you were to have another thalidomide experience, where a product was approved and caused harm, but it was approved either by going to the top of the line or under one of these expedited third party reviews?" I am no liability expert, but our job is to avoid that problem. The reforms that we would accept would be reforms that still give the FDA the ultimate authority to protect the health and safety of the public. In the past, and in the product liability bill, we have opposed the granting of immunity to a product because it had received approval by a government agency–whether it was the FDA or another agency–on the grounds that every product that is approved has a post-market surveillance period as well. Now we pride ourselves in having a far lower rate of recalls based on post-market surveillance than does Europe, which although it approves some things more quickly, has to call back a lot more things than we do.

The liability questions remain and should be sobering concerns for people who want to speed up the front end, but forget that the post-market surveillance is an area we also have to be concerned about. We must keep the recalls at a minimum and not have to answer to the American public for irresponsible or too expedited reviews that didn't take into account all available information. All available information does not always give you everything you're going to know after a couple of years on a mass market. We try to move very quickly in those cases.

31. *See supra* note 27.

Passing any bill is a challenge; many are proposed, few pass. We view the House bills at this point as being too far beyond the line that we can accept, for many reasons which I am sure you have heard in recent testimony.[32] We prefer to start with the Kassebaum bill and if we can make the compromises regarding the "hammers" and the medical devices, we believe that this is a vehicle that can move. If those changes cannot be made, then we would rather wait and do it right than to hurry up and have to do it again because we would have a difficult time taking the steps beyond the lines that we think are fair.

We are not afraid of criticism of the FDA. We have ourselves criticized the FDA, and we have been very aggressive in changing the FDA. We have been very aggressive in changing the executive branch via the Reinventing Government program. We have tried to make the entire government more user-friendly, online, and more responsive, but the public asks us to protect them from certain things. If there is ever a clear function of government, it is for the FDA to make sure that our foods, drugs, and devices are safe. This does not mean that review must be slow, expensive or tedious, but it does mean it has to be careful and disinterested.

Many of the critics of the FDA are criticizing it because they would prefer that most of it go away. Some groups have even suggested that we remove from the mission statement of the FDA the task to protect the public health and safety, and focus instead on the quick and expeditious review of drugs, devices, and foods. This is not only beyond the line, but beyond the pale. As Abraham Lincoln once said, "He has a right to criticize who has a heart to help."

The biotechnology industry has had a heart to help. They have been front-and-center in helping us devise many of the reforms we announced in the Reinventing Government initiative and in very productive discussions with the Administration on the types of changes we can make in the legislation. But this is not just a case of if we do it wrong this time, when are we going to have the time to do it again? This is a case where we cannot afford not to do it right the first time because we do not want to have to go through the pain we would go through to find out that we have to do it over. That is why we support careful, deliberative reform and will oppose any reform that does not meet those standards.

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32. *FDA Approval Process: David A. Kessler, M.D. Commissioner of Food and Drugs Department of Health and Human Services Before the Subcommittee on Health and Environment*, 104th Cong., 2d Sess. (1996) (statement of David Kessler, M.D., Commissioner, FDA).