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New FDA Commissioner's Top Priorities: FDAMA Implementation, Agency's Science

FDA Commissioner Jane Henney said her two top priorities will be implementation of the FDA Modernization Act and "strengthening the science base of the agency."

Observers familiar with Henney's previous stint at FDA and her career outside the agency said her style is likely to be geared toward optimizing management rather than generating headlines.

"Management" is a logical priority for Henney, since the challenges she now faces include implementation of initiatives launched by her

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In Brief:

Ames, Rowley, Win National Science Medals; New Building Planned For Pittsburgh Center

AMONG THE winners of the National Medal of Science last month were **Bruce Ames**, director of the National Institute of Environmental Health Sciences at University of California in Berkeley, for his work on mutation, cancer and aging; **Janet Rowley**, professor at the University of Chicago, for her discovery of chromosomal translocations in cancer; **Biogen Inc**., for vaccine work and developing pharmaceuticals for patients worldwide; and **Bristol-Myers Squibb Co.** for developing clinical trials which have become industry models. . . . **UPMC** Health System plans to build a $104 million research, clinical and office facility on the UPMC Shadyside campus to serve as the hub of the University of Pittsburgh Cancer Institute's treatment and research activities. The 295,000 square-foot facility, partially funded through philanthropic donations, will accommodate 250 new scientists and clinicians. Groundbreaking will begin this spring. . . . **RENA PASICK** has been named Director, Prevention Sciences, Northern California Cancer Center. Pasick has served as NCCC associate director for 10 years. She succeeds **Robert Hiatt**, who became deputy director of the NCI Division of Cancer Control and Population Sciences. **Regina Otero-Sabogal** has been named NCCC's Associate Director, Prevention Services. . . . **UNIVERSITY OF PENNSYLVANIA** School of Medicine has been awarded a five-year, $10 million program project grant by NCI. The grant will fund a study called "WISE: Women's Insights and Shared Experiences," investigating hormone-induced female cancers. **Brian Strom** is principal investigator of the study. . . . **LAWRENCE WILLHITE**, 55, a program facilities manager at NCI since 1972, died Dec. 7 at his home in Kensington, MD, after a heart attack.

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"Strengthening FDA's Science" Is A Top Priority For Henney

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predecessor, David Kessler, as well as the regulations forced on the agency by Congressional FDA-bashers. Kessler left the agency in 1996, after a six-year tenure marked by controversy over his aggressive efforts to expand the agency's role.

"To meet the next level of change and challenge within FDA-the-organization, we will need to commit ourselves to the management principle that the best organizations find ways to constantly improve themselves," said Henney in a speech before the Food and Drug Law Institute Dec. 16, the day after she was sworn in by Vice President Al Gore.

Henney, an oncologist who left NCI as deputy director in 1985, most recently served as vice president of the University of New Mexico Health Sciences Center. From 1992 to 1994, she was deputy commissioner for operations at FDA.

FDAMA implementation alone will keep Henney busy, attorneys familiar with the law said. The law requires the agency to develop a massive number of regulations by specific implementation dates.

Henney's second stated priority, "to strengthen the science base," has been widely interpreted as support for retaining an intramural research capability at the agency. In recent years, industry groups said FDA scientists should devote their attention to prompt review of applications rather than bench research. However, a review of the agency's science by an external advisory group chaired by David Korn, of Stanford University, recommended that FDA retain and strengthen its research program.

In testimony before the Senate Committee on Labor and Human Resources during her confirmation hearing Sept. 2, Henney indicated that strengthening FDA's research program would help the agency retain scientists.

"It should concern us all that, at the very time the public and private research enterprise in this country is flourishing, one of our essential regulatory agencies may have difficulty recruiting and retaining strong scientists," she said. "Certainly not all scientists need to be engaged in active bench research, and there may be many opportunities to develop alliances with other public agencies, but together we must find ways and means to keep the science base of the agency from eroding."

The day after her swearing in, Henney elaborated on this theme:

"Science must support and guide the critical policy decisions that we make. We must apply scientific principles to our product reviews. Our inspectors must continue to receive scientific training to make good decisions in the field.

"We need to be at the top of our scientific game. Thus, we will need to pay particular attention to improving our recruitment and retention of personnel, and leveraging the intellectual power of other science-based governmental agencies and academia.

"It is quite clear that the investments made in both basic and applied research by the National Institutes of Health and the pharmaceutical, biotech, and medical device industries will result in a burgeoning growth of new products that will need to come to the marketplace. FDA must have the scientific sophistication needed to understand and to be able to adequately evaluate these new products. I am committed to seeing that our scientific expertise matches the complexity of the new products moving toward the market."

Other priorities Henney listed in the speech included ensuring food safety, the safety of the blood supply, and regulation of tobacco. FDA regulation of tobacco currently is tied up in court appeals. However, Henney's management style in dealing with these issues is likely to differ from Kessler's,

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partly because of her emphasis on consensus-building, and partly because the times have changed, observers said.

Some of the logistical problems Henney will face are inherent in the closed nature of her agency.

"I am deeply committed to building bridges of communication and breaking down the barriers that have kept the agency from being as effective and productive as it should be," Henney said in her Senate testimony.

While other research institutions, particularly NIH, rely on the support of professional societies and advocacy groups, FDA is so much of a "black box" that few outside groups that would ordinarily support the agency in scuffles on Capitol Hill are in a position to do so. The lack of transparency has another consequence: the agency's critics are often spectacularly uninformed while potential allies often lack the perseverance required to grasp FDA issues.

In fiscal 1999, the agency's traditional problems are likely to be exacerbated by a budgetary shortfall. Because the number of new product applications dropped in FY98 by nearly 8 percent and efficacy supplements fell by 18 percent, the user fees collected by the agency through the Prescription Drug User Fee Act are down. According to agency estimates, the agency is facing a $165 million shortfall.

Last August and September, the agency held a series of "stakeholder" meetings. A major finding, not surprisingly, was a need for better communication.

"Absent PDUFA funds, the agency's budget is flat or declining," Carl Dixon, president and executive director of the Kidney Cancer Association, of Evanston, IL, said to **The Cancer Letter**. Patient groups could become advocates for FDA funding if the agency were more open to public involvement, he said. "The problem is that the agency's budget process is not transparent," Dixon said.

Dixon, whose organization had lobbied for Henney's confirmation, met with Henney Dec. 4, along with representatives from the Oncology Nursing Society, of Pittsburgh, and the Alliance for Lung Cancer Support and Education, of Bellview, WA.

"We came away very impressed with Dr. Henney's commitment to a more open FDA and with a real hope that we will be able to work with her to resolve issues that we are all concerned about," Dixon said. "She is someone who patient groups can work with. She will be a conscientious administrator, not a bold innovator. I think that's what Congress wanted."

As Henney takes over at FDA, and increasing number of patient groups are expressing an interest in working with the agency—and monitoring it.

"The breast cancer advocacy community expects a great deal from Jane Henney," said Fran Visco, president of the National Breast Cancer Coalition and a member of the President's Cancer Panel. "We expect her to appreciate the importance of the involvement of trained consumer activists in all FDA decision making. We also expect that she will bring back the appropriate balance among safety and efficacy issues and industry and political pressures for rapid approval of new interventions."

Henney's immediate challenge is to form a management team. Two of the five deputy commissioners who reported to Kessler have left the agency.

William Schultz, deputy commissioner for policy, announced his departure Dec. 7, and Deputy Commissioner Mary Pendergast left last year. Michael Friedman, who led the agency as acting commissioner for two years and was considered for a time the front-runner for the commissioner's job, has returned to his post as deputy commissioner for operations.

Several observers and insiders said Henney is likely to take a greater hands-on role in running the agency than did Kessler, who delegated most management decisions to the deputies.

Some clues about the future structure of the agency are expected to emerge after an internal task force completes management plan for Henney.

The task force is headed by Linda Suydam, associate commissioner for strategic management. Suydam was Henney's associate commissioner for operations at FDA, then was recruited by Henney to follow her to the University of New Mexico. After a stint as associate vice president for planning and development at the university, Suydam returned to FDA last July. An FDA spokesman said the management plan has not yet been completed.

Uncertainty notwithstanding, FDA several staff members said they felt a sense of relief that the agency now has a Congressionally-sanctioned leader.

"It will be good to have a permanent commissioner again," an FDA staff member said to **The Cancer Letter**. "We probably will not be stepping back from critical issues. Dr. Henney will

simply have a different style."

The full text of Henney's Dec. 16 speech is available from the FDA website at http://www.fda.gov/speeches/jeh121698.html Henney's Senate testimony is available at http://www.senate.gov/~labor/hear/09028hrg/henney.htm

Senators Question Henney

In her remarks to the Food and Drug Law Institute Dec. 15, FDA Commissioner Jane Henney said that she declined the offer for a question-and-answer period following her speech. "Since the Senate provided me the opportunity to answer so many questions during the confirmation process, I wasn't sure I had any new answers left," she joked.

The Senate Labor and Human Resources Committee presented Henney with a list of 140 questions prior to the Sept. 2 confirmation hearing. After the hearing, the committee asked her to provide written responses to another 113 questions.

Henney's answers provide a view of the new commissioner's thinking on a variety of issues including new drug, biologics, and device review, patient involvement in FDA decision making, stem cell research, and cloning. Some of the post-hearing questions and Henney's answers follow:

Questions from Chairman James Jeffords

The following questions were proposed by cancer patient organizations:

(a) Please state your views on the benefits of consolidating the review and approval of cancer therapies and diagnostics into one central division or office.

I have not reviewed in depth the benefits of consolidating the review and approval of all the various cancer therapies and diagnostics into one central office. However, I do believe that FDA should strive for consistency in the review of cancer-related products. Currently, I understand that the Agency has attempted to assign review of the various types of cancer-related products to the divisions in which experts most familiar with the special features of the different products are located. If I am confirmed, I would be interested in reviewing a wide range of possible strategies for how to expedite and facilitate consistency in the review of cancer-related products across the Agency. Moreover, because of the important role that patient advocates have played in research, clinical trials, and the development of quality drugs, it would be my intention to consult with them during this review of possible strategies.

(b) Many in the patient community believe that the Office of Special Health Issues is a model of how the FDA should integrate its activities with the public. Do you agree? Do you have other suggestions for integrating the patient community into FDA processes?

In my opinion, the Office of Special Health Issues has done an excellent job of responding to the patient community and helping patients understand and work with FDA. As important, I think this office has helped FDA to better serve and understand patients, particularly those suffering from serious and life-threatening illnesses. I think the Agency needs to continue to find ways of making valuable information available to patients and opening its processes to the patient community.

Do you believe that the current FDA pre-approval requirements for showing drug safety are adequate to the task that they are designed to perform, or do you propose that they be modified? Please explain.

In my opinion, FDA's current pre-approval requirements for showing drug safety are adequate. Indeed, the United States has a record in recent years of having the world's safest drugs, in relation to other nations.

Do you believe that the current FDA post-market surveillance program for adverse drug reactions undetected during pre-market review is adequate to the task it is designed to perform, or do you propose that it be modified? Please explain.

Given the tremendous importance of this issue, I think it is critical that, if confirmed, I review FDA's current post-marketing surveillance program in greater detail before concluding whether or not it is adequate to the task. I would welcome input from the Congress, industry, consumers and health professionals in this regard. I think it is important first to determine the scope and extent of the problem, and before proceeding, I would intend to consult with all interested parties on an appropriate solution.

Of course, some improvements have recently been made, such as the creation of the Medwatch system for adverse event reporting and improvements in the automation of report filing and analysis. More needs to be done, and I plan to give this issue my attention. Of particular importance to improving the system will be effective collaboration with industry, physicians, and other organizations collecting such data (such as the U.S. Pharmacopeia).

Do you believe increased FDA post-market surveillance of drugs would have an effect on reducing the frequency of known, preventable side-effects of the type reported in the media in recent months?

If confirmed, one of the issues I would want to review in this area would be whether increased FDA post-market surveillance would have reduced the frequency of side effects for products like Posicor, Duract, or Fenphen (the combination of fenfluramine and phentermine), which were the subject of stories in the press in 1998. It seems likely, however, that increased post-market surveillance would detect adverse reactions to drugs sooner and in larger numbers. Through greater post-market experience with a drug, FDA might learn of ways to reduce the frequency of known side-effects and respond more quickly.

In oral testimony, you indicated that FDA has a role to play with regard to reducing the frequency of preventable adverse drug events. I understand preventable drug related morbidity to be attributable to poor quality care; untreated indications; improper drug selection; subtherapeutic dosing; failure of the patient to receive a drug; drug interactions with other drugs, foods, or disease, overdose, known adverse drug reactions; and drug use without a valid medical indication. Please describe what role you believe FDA has, if any, in each of these nine areas?

As the question indicates, drug related morbidity may arise secondary to various causes. Because FDA does not regulate the practice of medicine, the Agency does not play a direct role when patients are harmed by poor quality care or untreated indications. Injury that results from medication errors, such as improper drug selection, subtherapeutic dosing, failure of a patient to receive a drug, and overdosing, typically result from errors in prescribing, drug administration, or filling drug orders. FDA's role in these instances generally is limited to conveying drug information to health care professionals and patients to allow them to prescribe drugs and use drugs in ways that minimize adverse reactions. When patients are harmed by known adverse drug reactions, drug interactions, and drug use without a valid medical indication, FDA may play a larger role than only furnishing information to health professionals and the public. While prompt communication with health care professionals and patients usually suffices, sometimes FDA has to take additional steps. Recently, for example, the labeling changes and "Dear Doctor" letter for the drug Duract that were requested by FDA did not adequately reduce the risk of severe liver damage due to prescribing the drug for a longer time than recommended in the labeling. FDA then concluded that the drug could not be marketed safely and the manufacturer voluntarily withdrew the drug from the market.

Please explain what you mean by "enhancing FDA's science base"? Bearing in mind FDA's statutorily defined mission statement, what is the purpose of enhancing FDA's science base?

FDA is responsible for ensuring the safety and efficacy of a wide range of products. For example, the Agency must act on applications to market new food additives, drugs, biologics, medical devices and animal drugs. In order to bring safe and effective products to market as soon as possible, FDA must make decisions on a daily basis that are grounded in the best science.

In this connection, "enhancing FDA's science base" means recruiting and retaining the highest quality scientific talent available. The purpose of enhancing the science base, therefore, is directly linked to carrying out FDA's statutorily defined mission.

What plans do you have to define "least burdensome" and what remedy will be available to product sponsors in instances of disagreement with FDA on the application of this standard?

If confirmed, I will work to ensure that FDA interprets the "least burdensome" provision of FDAMA consistent with the letter and spirit of the law. I interpret the least burdensome appropriate means of evaluating device effectiveness for PMA approval to mean that, after considering the nature of the device and its proposed conditions of use, the Agency requests only the type and extent of data that are needed to establish a reasonable assurance that the device is safe and effective. In the 510(k) context, the least burdensome way of showing equivalence will vary depending on the similarity of a device to its predicate(s) and the public health significance of any differences. I understand that CDRH has taken steps to train its reviewers to ensure that they understand the importance of identifying the least burdensome path to marketing. If I am confirmed, I will examine whether guidance, which includes examples of the least burdensome means, would ensure implementation of this standard consistent with the spirit of the law.

If a product sponsor disagrees with FDA on the application of this standard, mechanisms to appeal should be available. FDA's regulations provide applicants with several mechanisms to resolve scientific controversies, including informal appeals through the supervisory chain, consideration by an advisory committee, as well as a more formal administrative review.

Do you believe that once FDA has approved a generic drug as therapeutically equivalent and substitutable to a branded drug, that this decision should apply uniformly across the country?

Do you believe that there is, or is not, a scientific basis for questioning FDA determinations on bioequivalence and substitutability of Narrow Therapeutic Index drugs?

As an oncologist, do you agree that a physician should be notified of any modification to a prescription he or she wrote, such as a switch from one brand name drug to another, from brand to generic, or from one generic to another generic? Is this more important for Narrow Therapeutic Index drugs?

All state formulary boards should be confident that FDA's approval of a drug as therapeutically equivalent means that the generic drug can be expected to have the same therapeutic effect as the branded drug and may be safely substituted.

In answer to the second question, I do not believe it would be appropriate to give a categorical response. Interested parties should always be free to question any FDA determination.

While I have not reviewed the third issue in detail, it seems to me that if the drugs have been rated therapeutically equivalent, the substituted drug can be expected to perform the same as the drug for which the prescription was written. I have not had the opportunity to deter-

mine whether, given the similarity in performance of the drugs, there are other reasons physicians should be notified of modifications to prescriptions. There may be a stronger case for such notification where the modification involved drugs that have a narrow therapeutic index.

At the hearing you spoke in very general terms about differences in approach between you and Dr. Kessler. Please identify any specific issue, policy, or aspect of Dr. Kessler's tenure at the FDA with which, with the benefit of hindsight, you disagree.

It has been my privilege to work for a number of individuals for whom I have had admiration and respect. Without exception, on occasion I found myself differing with decisions or actions taken by these individuals. I do not believe that it is professionally or personally appropriate to publicly air examples of such disagreements.

What I hope the Committee will find to be germane is my commitment to a certain style and process as Commissioner. As I indicated to the Committee, if I am confirmed, you will find me to be open, fair and forthright and dedicated to the task of seeing that safe and effective products are brought to the market in a timely fashion.

Questions From Sen. Dan Coats

At the nomination hearing, you stated support for the concept and practice of Agency/industry collaboration. How would you reconcile this perspective with the recent FDA announcement that it will not share with industry or public interest groups its thoughts or solicit theirs regarding the manner in which the law should be implemented prior to publishing guidance or proposed regulations. Will you as Commissioner commit to reverse this policy and allow collaborative meetings to occur before the issuance of a guidance document or regulation?

I am unaware of any decision by FDA to refrain from meeting or discussing FDAMA implementation issues prior to public dissemination of guidance documents, regulations, and other issuance designed to implement FDAMA. I have been informed that the Agency made a decision to rely, to the extent possible, on the processes that it has in place, namely, notice and comment rulemaking and Good Guidance Practices. At the same time, it did recognize that there would be times when it would be important to meet with outside groups to hear their views on implementation issues and to discuss drafts of FDAMA documents that were made available to the public at large.

It is my understanding that the Agency has engaged in such discussions with respect to FDAMA implementation and on a wide range of other guidances and regulations, consistent with the Administrative Procedures Act. In any event, regardless of the Agency's past practice, I am committed to ensuring that FDA has an extremely open process and that the Agency actively solicits industry and public input as part of the issuance of guidance documents and regulations.

There is concern with the administration's continued interest in funding FDA's premarket device review program with user fees. In your response to the Committee's written questions you note that historically user fees have only been implemented successfully when there is consensus. Please clarify whether there are any circumstances in which you would pursue device user fees in absence of such consensus.

If confirmed, I will be a very strong proponent of an FDA budget that assures adequate funding for the Agency to accomplish its mission of promoting and protecting the public health. I also would expect to support the Administration's annual budget.

As I stated in response to the Committee's written questions, consensus among the Agency, the Congress, industry, and consumers has been necessary for user fees to be successful. I do not foresee device user fees being implemented in the absence of such consensus. If confirmed, I intend to focus my personal attention on implementation of the third party review program and other innovative steps that I believe can help FDA maximize its resources and expedite product review times.

At the nomination hearing, you voiced strong commitment to the concept and practice of contracting with outside experts to supplement FDA's own staff to avoid PMA review delays, or to review certain portions of PMAs that may present novel scientific issues for which FDA has no in-house expertise. Does FDA currently budget a certain amount each year for contracts with outside experts for the purpose of assisting with product reviews? In your internal planning, will you commit to setting aside funds each year for this purpose? How much?

It is my understanding that the Agency is free to contract with outside experts regardless of whether particular funds are set aside for this purpose. I would like to have the opportunity, if confirmed, to review all elements of the Agency's budget. I certainly intend to assess how the Agency can most effectively use this contracting authority.

You define the concept of "least burdensome" necessary to show effectiveness as types of trials that "are the most likely to produce the most useful clinical information in the shortest amount of time." Since neither the legislative history nor the law incorporates that concept, would you further explain it so we understand how your definition relates to the "least burdensome" requirement?

I believe that FDA should work closely with the sponsors of clinical trials to decide what type(s) of trials are the most likely to produce the most useful clinical information in the shortest amount of time. I interpret the "least burdensome" requirement to mean that, after considering the nature of the device and its proposed conditions of use, the Agency requests only the type and extent of data that are needed to establish a reasonable assur-

ance that the device is effective.

There is concern over the FDA draft guidance proposing to restrict most of the health plans and Pharmacy Benefit Managers in America from comparing drugs and communicating formulary information. There is concern that this issue wasn't raised during FDAMA discussions. There is also concern that FDA was reaching far beyond its jurisdiction over drug manufacturers into a marketplace that it doesn't really understand. Are you in agreement with this draft guidance?

It is my understanding that numerous concerns have been raised with respect to FDA's draft guidance concerning pharmacy benefit managers. If confirmed, I intend to thoroughly review the issue before reaching any decision on what the Agency's role should be with respect to regulating the information about drugs that is disseminated by health care plans and pharmacy benefit managers.

Do you believe health plans and their pharmacy benefit managers have the right to choose drugs they consider best and communicate those choices to doctors, pharmacists, and patients?

I do believe that health care plans and pharmacy benefit managers have the right to choose drugs and to communicate their choices to doctors, pharmacists, and patients so long as they comply with any applicable state and federal laws.

Questions From Sen. Judd Gregg

What thoughts do you have for the implementation of FDAMA in light of the recent court decision in the WLF v. FDA case on the distribution of off-label information and the conduct of Continuing Legal Education? How will FDA implement the Court's decision?

First, let me say that I believe that the off-label provision of FDAMA is a creative and innovative way to deal with a difficult issue. This provision will allow companies to provide physicians with balanced information about off-label uses. But it also increases the incentive to do research.

With respect to your question, it is my understanding that the Agency has asked the court for clarification as to whether the WLF v. FDA decision applies to the FDAMA provision on off-label information. If the court determines that the opinion does not apply to FDAMA, FDA should implement the statutory provision consistent with the letter and spirit of the law.

Everyone agrees that the more information patients have about healthcare the better our healthcare system. How do you believe patient information should be delivered and by whom? Do you believe the current package insert and "brief summary" requirements are effective? What steps would you take to ensure that FDA personnel reviewing Direct-to-Consumer advertising have the training and professional background appropriate for the regulation of advertising directed at consumers through the lay media?

While I believe it should be subject to ongoing evaluation and improvement, I do believe the current package insert and brief summary requirements have enhanced the delivery of important information to patients. If confirmed as Commissioner, I will work hard to ensure that the Agency's drug advertising review program has people with the training and professional background appropriate for this responsibility.

Questions From Sen. Bill Frist

Do you see a difference between advertising and the dissemination of peer-reviewed journal articles?

Yes. There clearly is a difference between traditional advertising and promotion of a product on the one hand, and the dissemination of peer-reviewed journal articles on the other. Typically, advertising is written by the drug company and designed to promote its product. Peer review journal articles typically are written by independent scientists and are often used by physicians in making medical decisions with respect to their patients.

Do you agree that FDA's authority to establish restriction on drugs and devices does not in any way restrain physicians from prescribing drugs or devices for off-label uses?

In general, FDA does not have the authority to restrain physicians from prescribing drugs or devices for off label uses. In certain situations, however, it does have authority to impose restrictions. For example, there is an explicit provision in the device law under which the Agency may require that only certain medical specialities prescribe a particular device. It is my understanding that the Agency also imposed restrictions on the use of the drug Thalidomide in its recent approval. For example, only physicians who are registered in the manufacturer's "System for Thalidomide Education and Prescribing Safety" program may prescribe the drug.

In your letter to the Committee dated August 24, 1998, you stated that "the Agency has taken the position that it has the authority to regulate the conduct of research to clone a human being." Would this authority include the ability to regulate basic research in laboratories that have no intention of applying for an IND?

Whether the Agency has the authority to regulate basic research depends on whether the purpose of that research, in this case, is to clone a human being, not whether the intention of the researchers is to apply for an IND. Generally, the exercise of FDA's authority over basic research is triggered by the filing of an IND.

Is there a difference between somatic cell therapy and germline therapy in terms of your intended regulatory approach?

I understand that it is the Agency's position that it has authority to regulate both types of therapy. This is an enormously complex area, and I look forward to reviewing carefully FDA's policy.

Do you support the use or development of hu-

man embryos, including the preimplantation embryo, for research or therapeutic purposes? Would you consider such INDs or PMAs?

The use or development of human embryos for research or therapeutic purposes clearly raises difficult ethical issues and choices. I understand and respect the restrictions that have been imposed on the use of federal funds in this area. If human embryos were to be used or developed for clinical research or therapeutic purposes, it would be FDA's responsibility to see that all issues of safety and effectiveness were dealt with appropriately; this generally would be done through the IND and investigational device exemption (IDE) processes.

Wouldn't the FDA only have authority to intervene at the stage where this research would become a therapy, drug or device? Could you please explain?

I believe it is the Agency's position that it has authority to regulate research conducted for clinical or therapeutic purposes. I believe this is a complicated legal question, that involves emerging, complex scientific questions. I would intend to look at these issues very carefully if I am confirmed.

Should FDA regulate a researcher who plans to create predominantly human but part animal embryo and/or fetus?

I have never considered this issue. However, it would seem reasonable that FDA should regulate research dealing with such embryos in the same manner as it regulates research involving an entirely human embryo or fetus. I would clearly want additional input from the scientific community and other concerned parties before formalizing a position on this important question.

Do you consider an embryo formed from the nucleus of a human somatic cell infused into a bovine oocyte a human embryo? How would you regulate this practice?

As with the previous question, I have never considered this issue, but I think that such an embryo should be regulated.

What is a human clone, in your opinion? Please address your remarks to the embryonic, fetal and infant stages of human development.

In my opinion, a cloned human being would be a person produced through a cellular copy of a pre-existing human being. My understanding is that with current technology a human clone, if developed, would go through the same embryonic, fetal, and infant stages as a non-cloned human.

Do you support the use of somatic cell nuclear transfer, using human genetic material, which results in an embryo, including the preimplantation embryo, for products useful for the cure, prevention, treatment of a condition of human beings?

I believe that somatic cell nuclear transfer may have great potential to assist in the cure, prevention, or treatment of a condition of human beings. However, using such technology to clone a human being raises profound ethical and moral questions. I support federal legislation that would make it illegal for anyone to create a human being through cloning.

Questions From Sen. Mitch Mcconnell

You stated that the FDA will continue those tobacco regulatory activities which the Fourth Circuit court's decision allows, and that you had no plan to expand on those activities while the case was being appealed. Does your statement mean that FDA will not request additional funding to its FY 1998 allocation for its enforcement plan regarding teen access until the jurisdictional issue is resolved?

My understanding is that the rules of the Fourth Circuit court do allow FDA to continue the current program regarding restricting teen access to tobacco products. The FY99 budget proposed by the Administration already includes funds beyond the FY98 allocation to strengthen that existing program. If confirmed, I will abide by final judicial or congressional action with respect to FDA's jurisdiction over tobacco products.

Do you plan to use any funds to classify tobacco products under the Act for purposes of regulation prior to final court or Congressional action?

I have no such plans.

Questions From Sen. Tom Harkin

I am very concerned about FDA contracting out the review of higher risk devices. What are your thoughts on this?

FDAMA provided FDA with specific authority to contract out product reviews, or portions thereof. I think that the Agency should consider utilizing such contracts, especially when the evaluation of new technologies requires specialized scientific or technical expertise. As Congress recognized in its structuring of the third party review program, however, the complexity and public health issues associated with the review of PMA devices are important factors to be considered. In consultation with industry, consumers, and other interested parties, I believe the Agency will need to exercise sound judgment as to the devices for which the contracting out authority is appropriate.

Would you be willing as Commissioner to convene a working group with biotech representatives to review the use of advisory panels and make recommendations as to how they might be improved to maximize their utility to FDA?

Clearly, there is a delicate balance between, on the one hand, giving advisory committees adequate freedom to raise issues they find pertinent, and on the other hand, ensuring that the advisory committees focus on those issues for which the Agency believes their advice will be most helpful.

If I am confirmed, I would be pleased to meet with biotechnology industry representatives to learn more about their concerns.

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