and a half and how it is just one battle in this ongoing conflict of ideas and really debate about the nature of our country that we have had since the beginning of this country. But there is a judgment day. There is a judgment day under our form of government, and that is when ordinary citizens exercise their right to go to the polls and to say whether they approve or disapprove of what we are doing here in this Chamber.

Whether you are a city councilman, county commissioner, Governor, Senator, Congressman, President of the United States, we are subject to the ultimate judgment of those voters, of those citizens, because we are a country that believes in the sovereignty of the people. And it is the people who will have the last word.

I believe our friends on the other side of the aisle who have exercised this tyranny of the minority have made a very dangerous gamble. Their gamble is, what they are betting is, that not enough people are really paying attention. Of course, that is part of what we have been trying to do, to make sure that people who are interested have an opportunity to understand what is going on here and what is at stake.

But ultimately, under our form of government, there can be no division in this body or anywhere else in this country about the fact that, ultimately, the American people will exercise the final judgment and determine who wins and who loses. That has not been decided today on this issue.

This is just one battle in that ongoing war leading up to that day of judgment. Ultimately, for those of us who run for public office, that is what determines whether we will continue to serve here in this body or in any other elected office in this Nation or not; whether we maintain the confidence of the people; whether the people believe that what we are doing here represents their interests as opposed to special interests. And if, in fact, they have confidence in our judgment, our honesty, integrity, and what it is we are trying to accomplish here, then they will say so by returning us to this place, or any other office of public service. So, ultimately, this battle has really been a skirmish in this ongoing conflict.

There is an important difference between those who would obstruct a bipartisan majority who want to confirm these fine nominees, and that is really the nature of the judicial branch of our Government.

I have had the honor for 13 years to serve my State in the judiciary before I was attorney general, and now in the Senate. I believe fervently that what the Framers intended by creating the judicial branch was not one where we had ideologues on the bench, or even politicians who were trying to advance a political or personal agenda. What they conceived and what has helped maintain the rule of law by determining the independence of the judiciary is that we will have rules that will govern all of us, and there will be disputes about those rules and the facts will be decided by independent judges, not ideologues, not those politicians on the bench, not somebody who has run for a particular platform to be nominated and confirmed to lifetime tenure.

The Framers' genius really was that that is a role they left to the representative branches of Government, the Congress and the executive branch, represented by the President. They conceived of a judiciary that would interpret the law and not make the law; that would interpret what the legislature's intent was, not promulgate public policy from the bench, or legislate from the bench. The legislation, they said, should come from the Congress. Once the Congress has determined the laws, then the President has a responsibility to execute the law.

It is a judiciary that serves as the impartial ''umpire.'' We all know that, in any sporting activity, an umpire who takes sides before the contest is inconsistent with the whole idea of fair play. We are talking about more than fair play here. We are talking about what kind of nation America is and what kind of nation America will become, whether we preserve this concept of an independent judiciary, unaffected by politics, that determines the law, not makes the law.

I believe James Madison, Alexander Hamilton, and others of the Founding Fathers, who so wisely conceived of this form of government, would literally roll in their graves if they heard some of the suggestions we have heard during this debate and elsewhere—that judges can, and perhaps should, be ideologues; and really what we are trying to do is achieve some sort of mythical balance to make sure we have enough conservatives and liberals and moderates on a multijudge bench, and somehow in this ''witch's brew'' we are going to come out with justice, with fairness; that people will know what the rules are ahead of time and be able to conform our conduct to what the rules are, so they can go about their business unafraid of being interfered with, molested, or sued.

Indeed, that is what we depend on, the knowledge of what the rules are, and that they will be administered by those who do not have a stake in the outcome, or have an ax to grind, or have a political or personal agenda. That is what our judges are supposed to be, not those who participate in a game of political football.

We do not want, as this process has seemed to degenerate into, judges who will precommit to the outcome of cases that may come before them before they have even heard the facts. In the Judiciary Committee, on which I serve, I have heard judicial nominees questioned about: How would you rule if such and so happened? What is your view of the 14th amendment or the 5th amendment? Assuming this given set of facts, how would you rule in that case?

Those questions are entirely inappropriate. We don't want judges, and we should not confirm judges, who would prejudge a hypothetical set of facts. We want judges who have an open mind and a commitment to the rule of law, and who will enforce that law impartially, without regard to who wins or loses.

If what we are doing here jeopardizes the rule of law, we will have done great damage not only to this body but to our country.

Mr. President, I thank my colleagues for patiently listening after this long debate. But I believed it was important to make some of these points.

I yield the floor and suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. ENSIGN. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDENT pro tempore. Without objection, it is so ordered.

PRAYER

The PRESIDENT pro tempore. The hour of 12 noon having arrived and the Senate having been in continuous session since Wednesday, pursuant to the order of the Senate on February 29, 1960, the Senate will suspend while the Chaplain offers a prayer.

Today's prayer will be offered by our guest Chaplain, Rev. Leroy Gilbert, Pastor of Mount Gilead Baptist Church in Washington, DC.

The guest Chaplain offered the following prayer:

Eternal God, the God of grace and glory, the God whose giving knows no ending, the God who stretched the spangled heavens and made us speechless at the sight of His magnificent handiworks, we pause to invoke Your blessing upon our Nation, our Senators, and all those who serve them.

Lord, we pray that the work of this Body will equip every household in America with the resources to build strong and stable families. We pray that the Senators' tireless efforts will enable the people of America to stand strong for the principles that undergird our rights, liberties, and the pursuit of happiness. We pray, when citizens observe how this Senate conducts the business of our Nation, they will be inspired by how those from different political parties can work together to achieve a common purpose for the good of America.

As one Nation under God, may we always be protected by Your divine promises as recorded in Chapter 54 of Isaiah, which declares: ''This is the heritage of the servants of God . . . no weapon formed against you shall prosper . . . tyranny and terror will be far from you . . . whoever attacks you will surrender to you.'' To You, Almighty God who assures the faithful, ''I will make your way prosperous and you shall have good success,'' we pray. Amen.

The PRESIDENT pro tempore. In my capacity as the Senator from Alaska, I suggest the absence of a quorum.

The clerk will call the roll.

The assistant legislative clerk proceeded to call the roll.

Mr. FRIST. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

ANIMAL DRUG USER FEE ACT OF 2003

Mr. GREGG. Mr. President, on November 7, 2003, the Senate passed the Animal Drug User Fee Act of 2003 which authorizes animal drug user fees.

Performance goals, existing outside of the statute, accompany the authorization of animal drug user fees. These goals represent a realistic projection of what the Food and Drug Administration's Center for Veterinary Medicine can accomplish with industry cooperation. The Secretary of Health and Human Services forwarded these goals to the chairmen of the Senate Committee on Health, Education, Labor, and Pensions, and the House Committee on Energy and Commerce, in a document entitled ''Animal Drug User Fee Act Performance Goals and Procedures.'' According to Section 2 of ADUFA, ''The fees authorized by this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions . . . as set forth in the CONGRESSIONAL RECORD.''

Today, I am submitting for the RECORD this document, which was forwarded to the Committee on Health, Education, Labor, and Pensions on November 13, 2003, as well as the letter from Secretary Thompson that accompanied the transmittal of this document.

I ask unanimous consent they be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

THE SECRETARY OF HEALTH
AND HUMAN SERVICES,
Washington, DC, November 13, 2003.

Hon. JUDD GREGG,
Chairman, Committee on Health, Education, Labor and Pension,
U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: As you are aware, the Food and Drug Administration has been working with representatives of the veterinary pharmaceutical industry and staff of your Committee to design a new animal drug ''user fee'' proposal. Under this proposal, the additional revenues generated from fees paid by this industry would be dedicated for use in expediting the process for the review of animal drug applications, in accordance with performance goals that have been developed by FDA in consultation with the industry. S. 313, the ''Animal Drug User Fee Act of 2003'' reflects the fee mechanisms developed in these discussions. The performance goals are specific in the enclosure to this letter entitled, ''Animal Drug Under Fee Act Performance Goals and Procedures.'' I believe they represent a realistic projection of what FDA can accomplish with industry cooperation and the additional resources that would be provided by the bill and annual FDA appropriations that fully cover the costs of pay and inflation increases for the animal drug review process each year.

I appreciate the support of you and your staffs, and the assistance of other Members of the Committee.

Sincerely,

TOMMY G. THOMPSON.

ANIMAL DRUG USER FEE ACT PERFORMANCE GOALS AND PROCEDURES

The goals and procedures of the FDA Center for Veterinary Medicine (CVM) as agreed to under the ''Animal Drug User Fee Act of 2003'' are summarized as follows:

FIVE-YEAR GOALS (TO BE IMPLEMENTED BY SEPTEMBER 30, 2008)

1. Review and act on 90 percent of complete animal drug applications (NADAs) and reactivations of such applications within 180 days after submission date.

2. Review and act on 90 percent of nonmanufacturing supplemental animal drug applications (i.e., supplemental animal drug applications for which safety or effectiveness data are required) and reactivations of such supplemental applications within 180 days after submission date.

3. Review and act on 90 percent of manufacturing supplemental animal drug applications and reactivations of such supplemental applications within 120 days after submission date.

4. Review and act on 90 percent of investigational animal drug study submissions within 180 days after submission date.

5. Review and act on 90 percent of investigational animal drug submissions consisting of protocols, that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, without substantial data within 50 days after submission date.

6. Review and act on 90 percent of administrative animal drug applications (NADAs submitted after all scientific decisions have been made in the investigational animal drug process, i.e., prior to submission of the NADA) within 60 days after submission date.

The term ''review and act on'' is understood to mean the issuance of a complete action letter after the complete review of an animal drug application, supplemental animal drug application, or investigational animal drug submission which either (1) approves an animal drug application or supplemental animal drug application or notifies a sponsor that an investigational new animal drug submission is complete or (2) sets forth in detail the specific deficiencies in such animal drug application, supplemental animal drug application, or investigational animal drug submission and, where appropriate, the actions necessary to place such an application, supplemental application, or submission in condition for approval. Within 30 days of submission, FDA shall refuse to file an animal drug application, supplemental animal drug application, or their reactivation, which is determined to be insufficient on its face or otherwise of unacceptable quality for review upon initial inspection as per 21 CFR 514.110. Thus, the agency will refuse to file an application containing numbers or types of errors, or flaws in the development plan, sufficient to cause the quality of the entire submission to be questioned to the extent that it cannot reasonably be reviewed. Within 60 days of submission, FDA will refuse to review an investigational animal drug submission which is determined to be insufficient on its face or otherwise of unacceptable quality upon initial inspection using criteria and procedures similar to those found in 21 CFR 514.110. A decision to refuse to file an application or to refuse to review a submission as described above will result in the application or submission not being entered into the cohort upon which the relevant user fee goal is based. The Agency will keep a record of the numbers and types of such refusals and include them in its annual performance report.

FDA may request minor amendments to animal drug applications, supplemental animal drug applications, and investigational animal drug submissions. At its discretion, the Agency may extend an internal due date (but not a user fee goal) to allow for the complete review of an application or submission for which a minor amendment is requested. If a pending application is amended with significant changes, the amended application may be considered resubmitted, thereby effectively resetting the clock to the date FDA received the amendment. The Agency intends to establish the same policy for investigational animal drug submissions.

Sponsors are not required to submit study protocols for review. However, for each voluntarily submitted protocol for a study that the Agency and the sponsor consider to be an essential part of the basis for making the decision to approve or not approve an animal drug application or supplemental animal drug application, the Agency will issue an acknowledgement letter providing comments resulting from a complete review of the protocol. The acknowledgment letter will be as detailed as possible considering the quality and level of detail of the protocol submission, will include a succinct assessment of the protocol; and will state whether the Agency agrees, disagrees, or lacks sufficient information to reach a decision that the protocol design, execution plans and data analyses are adequate to achieve the objectives of the study. If the Agency determines that a protocol is acceptable, this represents an agreement that the data generated by the protocol can be used to support a safety or effectiveness decision regarding the subject animal drug. The fundamental agreement is that having agreed to the design, execution, or analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspectives on the issues of design, execution or analyses unless public or animal health concerns unrecognized at the time of protocol assessment under this process are evident.

INTERIM BACKLOG GOALS

1. Review and act on pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions within 24 months of initiation of user fee payments.

ADDITIONAL INTERIM GOALS

1. Fifty percent of FDA incremental review staff recruited and on-board by first quarter of FY 2006. Total staff increment on-board by end of FY 2008.

2. FDA will review all submissions in accordance with procedures for working within a queue. An application/submission that is not reviewed within the applicable Interim Application/Submission Goal time frame (noted below) will be reviewed with the highest possible priority among those pending.

INTERIM APPLICATION/SUBMISSION GOALS

FY 04—90 percent of:

Animal drug applications (NADAs) and reactivations of such applications received during FY 2003 are reviewed within 259 days.

Non-manufacturing supplemental animal drug applications and reactivations of such