October 12, 1999

HEALTH - ORGANS

The Honorable Thomas Bliley
Chairman
Committee on Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Bliley:

I am writing to express the Administration's strong opposition to the Organ Procurement and Transplantation Network Amendments of 1999 (H.R. 2418) that would reauthorize the National Organ Transplantation Act (NOTA), as amended. We have serious concerns that the bill would preserve existing inequities in the organ transplantation system and could result in potential harm to patients. We are committed to working with you and your colleagues in the Congress to develop NOTA reauthorization legislation that better reflects the recent recommendations of the Institute of Medicine (IOM) and that results in a fairer transplantation system for all patients in this country and their families.

As you know, we believe the current organ allocation policies established by the Organ Procurement and Transplantation Network (OPTN) are inequitable because patients with similar severities of illness are treated differently, depending on where they may live or at which transplant center they may be listed. For this reason, on April 2, 1998, the Department of Health and Human Services issued a Final Rule for the OPTN that establishes a framework for organ allocation policies, to be developed by the network, that are based on sound medical judgment, and that are fairer and more equitable for all parties. The IOM's Committee on Organ Procurement and Transplantation Policy, in its report of July 22, 1999, validated this regulatory framework. In response to the IOM report, as well as written comments submitted concerning the April 2 rule, and lengthy discussions with representatives of the transplant community, we are in the process of making revisions to improve the rule.

We have several serious concerns with H.R. 2418:

One important shortcoming is that H.R. 2418 does not require the standardization of patient listing practices and the broader sharing of organs, two items that we and the IOM consider essential to ensuring fairness in the system and optimal outcomes for patients.

In addition, we believe that H.R. 2418 raises serious Constitutional issues. For example, the bill provides for a delegation of governmental authority to a private entity without appropriate standards of federal review. Yet the bill does not stipulate that binding and enforceable policies for the OPTN be reviewed by the federal government; instead, it provides authority to promulgate policies exclusively to the OPTN. Without regulatory guidelines approved by the Department, the ability of the OPTN to enforce any policies that it develops pursuant to NOTA will likely be the subject of legal challenge, and the current problem of having unenforceable voluntary guidelines will persist.

H.R. 2418 contains provisions that grant extraordinary powers to the private sector to select and approve the federal contractor that manages the OPTN. This is inconsistent with existing principles of the federal acquisition process which promote fall and open competition in the awarding of federal contracts.

H.R. 2418 also would reduce the federal role in overseeing the OPTN, despite the recent recommendation from the IOM that, "The Department of Health and Human Services should exercise the legitimate oversight responsibilities assigned to it by the National Organ Transplant Act, and articulated in the Final Rule, to manage the system of organ procurement and transplantation in the public interest."

Finally, we are concerned that, although H.R. 2418 requires that the OPTN Board of Directors have physician representation of no less than 50 percent, it makes no such percentage requirements for transplant candidates, transplant recipients, and donor families, who we believe should have a significant representation on the Board.

In conclusion, Mr. Chairman, I regret that we must oppose H.R. 2418 because it provides extraordinary powers to a private entity and reduces the federal oversight role of our nation's organ procurement and transplantation system embodied in NOTA and affirmed by the IOM. If this bill were presented to the President, I would recommend that he veto it in its current form. I am hopeful that we can work together to develop reauthorization legislation that truly embodies the goals of NOTA and results in a fairer system for all patients in this country.

Sincerely,