

Arthur E. Dewey, of Maryland, to be Assistant Secretary of State (Population, Refugees, and Migration).

Adolfo Franco, of Virginia, to be an Assistant Administrator (Latin America and the Caribbean) of the United States Agency for International Development.

John V. Hanford, III, of Virginia, to be Ambassador at Large for International Religious Freedom.

Donna Hrinak, of Virginia, to be Ambassador to the Federative Republic of Brazil.

James McGee, of Florida, to be Ambassador to the Kingdom of Swaziland.

Kenneth P. Moorefield, of Florida, to be Ambassador to the Gabonese Republic and to serve concurrently and without additional compensation as Ambassador to the Democratic Republic of Sao Tome and Principe.

Josephine K. Olsen, of Maryland, to be Deputy Director of the Peace Corps.

John D. Ong, of Ohio, to be Ambassador to Norway.

Earl Phillips, Jr., of North Carolina, to be Ambassador to Barbados, and to serve concurrently and without additional compensation as Ambassador to St. Kitts and Nevis, Saint Lucia, Antigua and Barbuda, the Commonwealth of Dominica, Grenada, and Saint Vincent and the Grenadines.

Frederick Schiek, of Virginia, to be Deputy Administrator of the United States Agency for International Development.

Charles S. Shapiro, of Georgia, to be Ambassador to the Bolivarian Republic of Venezuela.

Gaddi H. Vasquez, of California, to be Director of the Peace Corps.

Roger Winter, of Maryland, to be an Assistant Administrator (Democracy, Conflict, and Humanitarian Assistance) of the United States Agency for International Development.

*Additional nominees to be announced.*

#### *Foreign Service Officer Promotion List*

Mr. Dobbins, et al., dated October 16, 2001. (With the exception of James Dobbins)

Mr. Hughes, et al., dated November 27, 2001.

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

#### PRIVILEGE OF THE FLOOR

Mr. BOND. Madam President, I ask unanimous consent that John Stoody, a detailee to my office from the Environmental Protection Agency, be given the privilege of the floor for the remainder of the consideration of S. 1731.

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

#### BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. REID. Madam President, this has been approved by the minority.

I ask unanimous consent that the Senate proceed to the immediate consideration of Calendar No. 271, S. 1789.

The PRESIDING OFFICER. The clerk will report the bill by title.

The senior assistant bill clerk read as follows:

A bill (S. 1789) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children.

There being no objection, the Senate proceeded to consider the bill.

Mr. KENNEDY. I congratulate my friend from Connecticut, Senator DODD, and my friend from Ohio, Senator DEWINE, for bringing us the Best Pharmaceuticals for Children Act. Since 1977, we've had great success increasing the number of studies of drugs in children, and it's important that we reauthorize pediatric exclusivity to continue this success. One improvement in this reauthorization is that section 4 of your bill will see to it that, when a drug company declines an FDA request to study its patented drug for children, the drug will nonetheless be studied for children.

Mr. DODD. That is correct.

Mr. KENNEDY. You bill has these studies being conducted by, for example, universities, hospitals, contract research organizations, and pediatric pharmacology units. The studies will happen after referral to the Foundation for the National Institutes of Health, which, if it has the money to do so, provides money to the NIH for it to fund the studies, or passes it on to the NIH to pay for the studies with money that the bill itself authorizes.

Mr. DEWINE. Yes, that's how the process works.

Mr. KENNEDY. And after the research is conducted, the results are submitted to the Secretary of Health of Human Services. Once the Secretary has received the results, the Secretary, through the FDA, analyzes the information from the studies and determines what is necessary to provide appropriate pediatric labeling of the drug.

Mr. DODD. Yes, that is what we intend.

Mr. KENNEDY. So, it is fair to conclude that pediatric research conducted by third parties, using a commercially available drug, and paid for by the Foundation of the National Institutes of Health or by NIH under your bill, will not infringe any patent on the drug and shall be considered to be an activity conducted for the purpose of development and submission of information to the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act?

Mr. DEWINE. Yes, I agree with that conclusion.

Mr. DEWINE. Madam President, I rise today to thank my colleagues for supporting and passing the conference report on a bill that Senator DODD and

I have been working on for some time. This bill, S. 1789, the Best Pharmaceuticals for Children Act, is reauthorization legislation designed to ensure that more medicines are tested for children and that useful prescribing and dosing information appears on labels.

Before I say anything else, I'd like to thank Senator DODD for his tireless efforts on behalf of children. He is a true champion for children. And, passage of our bill today, is just one more example of how he has dedicated so much of his time and energy to protect our Nation's kids, our Nation's future.

Our Best Pharmaceuticals bill is really vital in protecting our children when they are sick. This bill will make sure that we test drugs for kids on kids. Right now, most drugs are designed and tested on and for use by adults. Prescribing medicine for children is difficult for a variety of reasons. Proper dosing depends on a child's weight and metabolisms. Furthermore, children's bodies grow and change quickly. Children also may not give doctors accurate information about how medicines are affecting them, making diagnoses difficult, involving a large-degree of guess work.

A recent six-week study in Boston, at two of its most well-respected hospitals, found that over that time, 616 prescriptions written for children contained errors. Of those, 26 actually harmed children. Of the errors that were caught before the medication was administered, 18 could have been fatal. And, a study in the a recent Journal of the American Medical Association, found that medication errors in hospitals occur three times more frequently with children than with adults.

Four years ago, Senator DODD and I first learned that the vast majority of drugs in this country that came on the market every week, in fact over 80 percent, had never been formally tested or approved for pediatric use and therefore lacked even the most basic labeling information regarding dosing recommendations for children. When we found that out, we began writing what is now referred to as the pediatric exclusivity law. In the three years since that law went into effect, the FDA has issued about 200 written requests for pediatric studies.

Companies have undertaken over 400 pediatric studies, of which over 58 studies have been completed, for a wide range of critical diseases, including juvenile diabetes, the problem of pain, asthma, and hypertension.

Thirty-seven drugs have been granted pediatric exclusivity. Some studies generated by this incentive have led to essential dosing information. Take, for example, the drug, Luvox. Luvox is a drug prescribed to treat obsessive-compulsive disorder. Pediatric studies performed pursuant to our law have shown inadequate dosing for adolescents,