eral Register statements, 338 were fixed combinations, and of the 1,473 related drugs removed from the market, 1,345 were fixed combinations.

Senator NELSON. Are over-the-counter drugs included?

Dr. EDWARDS. No. There are a few OTC's but the majority are prescription drugs. There are 422 OTC prescription drugs reviewed by the National Academy. Although they have been published in the *Federal Register*, no action has been taken specifically. They are being reviewed as part of the over-the-counter drug review.

Senator NELSON. These drugs were reviewed by various classes?

Dr. EDWARDS. These are the over-the-counter drugs that are being reviewed class-by-class; yes.

In the months ahead, the drug industry will be carrying out, and the FDA will be assessing, the studies necessary on drugs which currently lack adequate evidence of efficacy. Drugs for which there is not adequate evidence of effectiveness will, as required by law, be removed from the market.

This has already been done on many fixed-dose combinations. In the months ahead, as the results of this study reach more elements of our society, there will be a major impact on the public, the medical profession, the drug industry, and Government. In the end, much that is good will come from this study to the ultimate benefit of the medical profession and the public. The panels of the NAS/NRC have clearly and objectively pointed out the problem that faces us in the drug area. One of the great strengths of the study is that it has been a constructive joint effort of the medical profession and the Federal Government.

Procedures set up by this administration will allow a fair and equitable resolution of these problems in the months ahead. No precipitant actions will be taken and whatever actions are taken will be guided by detailed and fair analysis of adequate scientific data.

A new and high standard has been established for establishing proof of drug efficacy and for the evaluation of combination drugs through our new regulations on adequate and well-controlled studies and our combination drug policy. This alone should be a major factor in improving therapeutics in this country. In time, ineffective drugs and irrational formulations will be removed from the market.

The effective drugs remaining will be clearly and accurately labeled so that physicians will have available to them the balanced information they need for rational drug use. Where possible, this information will be derived from adequate and well-controlled clinical studies.

To fulfill our obligation to keep physicans fully informed about drug efficacy, we will require all drug labeling and advertising to disclose the efficacy ratings of the products involved while required studies are being done to determine their efficacy. We have also taken appropriate steps to keep other Federal and State agencies informed of our actions in the Drug Efficacy Study Implementation.

In the months ahead, a number of drugs will fall by the wayside and many others will establish the evidence of efficacy required by law. A massive project such as this cannot be completed without arousing some emotions. Our policy in this and all matters facing the agency is clear—

We do have an emotional commitment, a simple one; this is to take the emotion out of our work. We are not interested in any kind of confrontation, in political or bureaucratic victories; we are moving very swiftly toward relationships based not on crusades or rhetoric but on matters of equity and justice and effectiveness.