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Drug Importation Issues

**Submitted to the
U.S. Department of Health and Human Services
Task Force on Drug Importation**

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Surgeon General Carmona and Task Force Members, it is an honor to be here today representing the National Hispanic Medical Association and the Hispanic-Serving Health Professions Schools, Inc. both non-profit associations dedicated to improving the health of Hispanics and other underserved in the United States.

According to the US Census, the Hispanic population is now the largest ethnic group in the U.S. and exists in nearly all major areas of the country – the group with the least proportion of persons with health insurance and access to health care according to key health system indicators. In addition, this group faces barriers to health care services based on language, cultural barriers and the severe lack of Hispanics in all levels of the health workforce, where Hispanic physicians for example are only 5% of the total US physicians. The 2002 Institute of Medicine's Report on Unequal Treatment discussed specific recommendations to facilitate the inclusion of more populations with cultural backgrounds. Furthermore, the IOM reports on quality have pointed to the need for a Patient-Centered approach in health policy in 2004. Both Senator Frist and Senator Daschle have introduced legislation that show us various pathways to eliminate health disparities in our health system and they include enhancing minority research and data collection, promoting programs to increase minority health professionals and strengthening the leadership of the Office of Minority Health and cultural competence curriculum development. I recommend that your deliberations include these recommendations.

Drug importation discussions, we feel, require a review of the public safety and feasibility as well as a cost/benefit analysis for the pharmaceutical distribution chain, as you are doing. However, we are interested in educating physicians and health providers about the inclusion of cultural principles into public health activities. You can provide an imported drug to a regional wholesaler, but the eventual distribution to the local pharmacy in the Hispanic neighborhood and moreover, the awareness of that new service to the community requires its own protocols of outreach and education and information sharing.

As the "Unequal Treatment" report demonstrates, a major effort is needed on the part of both private and public partners, to develop linguistically and culturally appropriate services in a drug importation process. At the Federal level, we feel that the FDA should partner with the Office of Minority Health and its Regional Minority Health Consultants to develop the culturally appropriate messages, marketing and product protocols. We recognize the importance of the OMH Center for Linguistic and Cultural Competence in Health Care for developing the CLAS Standards and other projects to show us how to navigate the system in health care. In addition, the OMH has been successful by the fact that Kaiser Permanente, NCQA, JAHCO, the medical school and residency programs accreditation bodies, the Family Practice CME Module Project and other major health institutions have adopted cultural competence principles and the CLAS Standards and are using them voluntarily. There is a momentum that this Task Force cannot ignore on the recognition that Quality Care is needed for our diverse communities in order to improve the health of all America.

NHMA feels strongly that there should be demonstration projects and research done by Hispanics with the community that demonstrates the effectiveness of any new interventions that impact on health care delivery. Lastly, you must consider including more diversity in the leadership bodies created as critical to making any new program a success.

Prescription Drugs and Hispanics

Use of Prescription Drugs

Hispanics are less likely to use prescription drugs. Indeed, policy focused on the increased access to prescription drugs should include educational efforts targeted to Hispanic community about the importance of therapy and the providers the importance of adequate treatment to all patients.

In 2003, the Department of Veteran Affairs studied 12 month use of antipsychotics in the VA in Minnesota. Antipsychotics less common for African Americans and Hispanics¹

According to the Ambulatory Medical Care Survey, utilization of antidepressant pharmacotherapy was less than half the rate for whites in 1994-95 in Hispanics and Blacks.²

Border Crossing Behavior

140 miles from the US-Mexico border, 14% had crossed the border to seek medical care 80% of the respondents were uninsured, 28% reported purchasing medications – antibiotics and pain meds highest³

A 2003 study of US residents purchasing medications in Mexico indicated they do so for various reasons and for chronic diseases, most often for antibiotics and the number 1 reason was prices.⁴

In El Paso, Texas, a study on purchasing prescription medications in Mexico, more than 80% of patients had purchased US prescription drugs without a prescription.⁵

¹ Copeland LA, et al. Racial disparity in the use of atypical antipsychotic medications among veterans. *Am J Psychiatry*. 2003 Oct;160(10):1817-22.

² Sclar DA, et al. Ethnicity and the prescribing of antidepressant pharmacotherapy: 1992-1995. *Harv Rev Psychiatry*. 1999 May-Jun;7(1):29-36.

³ Macias EP, Morales LS. Crossing the border for health care. *J Health Care PoorUnderserved*. 2001 Feb;12(1):77-87.

⁴ Calvillo JP. Pilot study of a survey of US residents purchasing medications in Mexico: demographics, reasons, and types of medications purchased. *Clin Ther*. 2003 Feb;25(2):561-77.

⁵ Casner PR. Purchasing prescription medication in Mexico without a prescription. *West J Med*. 1992 May;156(5):512-6.

Access to Information

The Institute for Communications Research of Texas Tech University conducted a phone survey of 522 adult Hispanics and only 13% used media for health information –the majority reported family and friends were the main source of health information.⁶

Issues of Licensure in Hispanic Communities

Los Angeles County Health Department created a new office that increased law enforcement to curb sale of illegal sale of pharmaceuticals by unlicensed vendors (clinics of foreign physicians unlicensed as well as pharmacies providing medications without prescription) –found 280 investigations, 121 arrests and \$4.5 million of drugs in first 20 months. The Department also started an educational program in those communities most affected by this behavior.⁷

The Canadian Medical Journal reported in 2000, about the increasing seniors taking buses to Canada to purchase medications with pharmacies who have physicians writing scripts nearby or in some cases sell without scripts.⁸

Task Force Key Questions

I. Scope and Volume of Imported Drugs

Products need to be subject to the same level of labeling, research, and critical debate before being subject to use for all populations in the US. I don't believe that certain drugs that are deemed under prescription in the US should be divided into 2 groups – one that has lesser risk and could be more acceptable to the public. The fear is that the lesser regulated product will be faster to be given to the poor and minority groups.

II. Pharmaceutical distribution chain and the modifications to assure safety of imported products

Importation should be limited to be able to better track the product, like the blood supply in the US.

Adequate reporting for foreign sources should be assured if quality problems are found with imported products by having a targeted communications technology system set-up to media companies, pharmacies, alert systems through the CDC.

⁶ Hudson JC. Hispanic preferences for health care providers and health care information. Health mark Q. 1996;14(1):67-83.

⁷ Fielding, JE, et al. Halting the illegal sale of prescription medications in Los Angeles County. J Public Health Manag Pract. 2001 May;7(3):59-64.

⁸ Korcok M. Cheap prescription drugs creating new brand of US tourist in Canada, Mexico. CMAJ. June 27 2000;162(13).

In addition, Hispanic Spanish-speaking communities need a special targeted approach with reimbursement for translators and interpreters for regional data banks for the pharmacies and health facilities involved.

III. Foreign health agencies role with safety of exported drugs to the US.

World Health Organization should be a partner to discuss this and include the responsibility of public health leadership to meet and develop safety protections or share current protections being utilized in other countries.

Certainly, for the Hispanic community, PAHO and the Latin American countries could be a focus of important discussion.

IV. Limitations that may inhibit Secretary's ability to certify the safety of imported drugs.

Inability to limit the underground trade that would develop when new distribution patterns are started by importation of drugs. Better to have checks and balances in the registration and inspections and recordkeeping and redundancies with oversight linked to the Federal government infrastructure and its contracting institutions.

There should be a feedback system that allows for rapid recall, linked to the CDC new information systems to relay information back to providers on a timely basis, as well as to connect with the international points of contact.

V. Estimate of agency resources and activities for recommendations of the Task Force.

Other than FDA---Homeland Security, CDC alert systems, Customs, HRSA educational curriculum for primary care workforce Clinics, Corrections, Migrant Clinics, DOJ,

OMH needs to be expanded for technical assistance and coordination of national efforts to increase diversity in the system. Hispanic issues as mentioned above. Demonstration programs needed and more Hispanic health research and the training of more officials in public health on Hispanic health issues.

VIII. New costs to provide assurances of import security.
This would include language and culturally appropriate services.

IX. Impact on drug research and development.
Need to continue to have R&D in the U.S. and to increase the focus on Hispanic research subjects and the need to develop physician practice networks in Hispanic communities.