Statement

Today, we the undersigned, have reaffirmed at the 10th anniversary symposium of Medwatcher Japan that the drug evaluation system has been extremely distorted internationally. Highly limited access to drug information and even distorted information generated by drug industries, and underlying conflict of interests among industry/regulatory authority/academics contribute to the current situation.

The issue of Iressa for lung cancer raises a serious concern about the drug approval process in Japan. Iressa has failed to prove overall survival benefit in as many as 4 superiority trials (INTACT-1 & -2, SWOG, ISEL), in addition to the non-inferiority trial (V15-32) that was required by the Japanese regulatory agency when marketing approval was given to the manufacturer. On the other hand, by March 2007, more than 700 patients had died from interstitial pneumonia associated with the drug.

There is no scientific evidence to justify the continued marketing of Iressa whatsoever. The approval of Iressa should be withdrawn immediately, with humanitarian consideration given to patients who are currently under treatment.

We hereby undertake to continue close coordination and cooperation internationally in order to strengthen the vigilance of drug approval procedures and postmarketing usage.

At Yakugai Ombudsperson "Medwatcher Japan" 10th Anniversary Symposium

Yakugai Ombudsperson “Medwatcher Japan”

Peter Lurie, Deputy Director, The Health Research Group at Public Citizen

Christophe Kopp, Prescrire Editor

The Informed Prescriber

NPO Japan Institute of Pharmacovigillance (Kusuri-no-Check)

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