UT Health San Antonio

27 February 2018

To Whom It May Concern:

I am Professor of Pharmacology and Psychiatry and the Robert A Welch Distinguished University Chair in Chemistry at the University of Texas Health Science Center in San Antonio, Texas. I have conducted drug abuse research for more 40 years, and I have held US Drug Enforcement Administration (DEA) Schedule I and Schedule II-V registrations for 28 years, in addition to State of Louisiana and State of Texas registrations.

As a scientist who has dedicated his entire career to studying drug abuse, I am keenly aware of the need to strike a balance between regulatory control of drugs to protect the public and the freedom for researchers to study drugs in order to advance our understanding of drug abuse and develop new treatments. My research program has three major goals: 1) understand the factors that cause drug abuse; 2) evaluate the abuse potential of new chemicals (largely for the pharmaceutical industry and regulatory agencies); and 3) develop new treatments for drug abuse. The success of each of these activities depends upon the availability of a wide variety of drugs – the primary tools that we use to study the brain and addiction – including controlled substances. Scientists need the freedom to pursue lines of research that they, the experts, deem important; for that to occur, they need to have access to drugs.

Current regulatory oversight of scientists working with controlled substances is a significant impediment to research, and further regulatory oversight, as would likely result from the Stop the Importation and Trafficking of Synthetic Analogues Act of 2017 (SITSA), would worsen this situation. Separate storage and record keeping that is currently required of anyone working with Schedule I compounds is a burden for many researchers and institutions that is not clearly reduced with the new Schedule A; moreover, it is unclear whether the new schedule A would facilitate better access to research tools for scientists. Despite having a DEA Schedule I registration for nearly 30 years without incident, when I want to study a Schedule I compound that is not already on my registration, I have to submit volumes of paperwork (much of it redundant with previous requests) as part of a request evaluated by the DEA and others. Decisions on my most recent requests have taken many months; those delays impede research and prevent scientists like me from responding quickly to public health issues (e.g., emergence of a new drug of abuse) that demand systematic study. Increased regulatory oversight of researchers regarding controlled substances would have no obvious impact in protecting public health while significantly decreasing the productivity of scientists.

Rational decisions as to whether a drug should be scheduled or whether it might be a useful medicine can be made only with solid scientific data, and those data can be collected only if scientists have appropriate access to drugs for their experiments. The scheduling of compounds based strictly on chemical structure is a concern since drugs that are nearly identical in structure can have dramatically different effects. For example, some drugs contributing to the current opioid epidemic and overdose crisis (e.g., heroin) are structurally very similar to the drugs used to treat opioid abuse (naltrexone) or rescue patients from opioid overdose (naloxone). Similarly, there is evidence that the toxic effects of some fentanyl derivatives are relatively insensitive to reversal by the only drug (naloxone) that is available for rescue from overdose; however, most researchers do not have a Schedule I registration so they cannot investigate this important question. Schedule A would add another category of registration, but would not improve access to important tools for scientists because under SITSA all Schedule I and Schedule A registrants would be required to submit requests to the Attorney General.

Additional regulatory oversight and scheduling of compounds without solid scientific evidence will not improve public health but will further impede the already difficult job of dedicated addiction researchers.

Respectfully,

Charles P France

Charles P France, PhD | *Robert A Welch Distinguished University Chair in Chemistry*
Department of Pharmacology | Mail Code 7764 | 7703 Floyd Curl Drive | San Antonio, Texas 78229-3900 USA
Voice: 210.567.6969 | Fax: 210.567.0104 | Email: france@uthscsa.edu