

# January 2016 NEWSLETTER

Dear members and readers, first we wish you all a fruitful and prosperous 2016, with hope that you will fulfill all your personal and professional goals this year. Second, we have introduced a new column written by well known specialists working in the field of addiction, under the heading: "Thoughts on addiction". We are looking forward to hearing your feedback on the matters raised at [office@isamweb.org](mailto:office@isamweb.org)

## THOUGHTS ON ADDICTION

**Jerome H. Jaffe** is a Clinical Professor of Psychiatry at the University of Maryland. He was appointed by US President Nixon as that nation's first Drug Czar and was responsible for the establishment of the policy which first allowed the use of methadone for opiate dependence in the US and the establishment of medication assisted programmes, therapeutic communities and detoxification programs.

**Charles O'Keefe** is a Professor in the department of Pharmacology at Virginia Commonwealth University. He was appointed by US President Carter as Deputy Director for International Affairs in the Office of Drug Abuse Policy. While president of Reckitt Benckiser Pharmaceuticals he was responsible for leading the effort to modify US policy allowing the office-based treatment of opiate dependence with buprenorphine and its FDA approval.

## LAAM Commentary

LAAM (l-alpha-acetyl methadol) was studied in the 1970's as an alternative to methadone for the treatment of opiate addiction, particularly for patients who had difficulty meeting the regulatory requirements of daily clinic visits and also for those for whom methadone had less than 24 hour efficacy. Federally funded clinical trials led eventually to its approval in the US in July, 1993. However, approval did not result in its being widely used. Many methadone clinics were paid on a per patient visit basis, and allowing patients to come to clinic only three times a week would have reduced their revenue substantially. LAAM was used primarily in Veterans' Administration and other clinics that did not receive payment on the basis of visit frequency. Later, reports in the literature noted Q-T interval prolongation and the risk of cardiac arrhythmias, and in 2001 the FDA required the addition of a black box warning on the LAAM label regarding the potential for cardiac arrhythmias and *torsade de pointes* (TdP).

During the clinical trials and between its approval in 1993 and the label modification in 2001, LAAM was prescribed for thousands of patients without significant reports of adverse events when compared to methadone and was particularly effective in those patients. Nevertheless, following the label revision requiring ECG monitoring and the approval of buprenorphine in 2003, the company that had licensed LAAM decided to voluntarily discontinue its distribution as a result of lagging sales.

In Europe, following advice of the CPMP\* that given the availability of methadone and buprenorphine and their comparative safety data the indication for LAAM should be restricted, the EMA\*, in contrast to the labeling action taken in the US by the FDA, suspended marketing authorization entirely.

In 2007 and 2010 petitions were filed with the US Food and Drug Administration requesting a determination that LAAM had not been withdrawn for safety or efficacy reasons and was therefore eligible for immediate approval as a generic product. In a 2009 letter to the FDA, The American Academy of Addiction Psychiatry pointed out that some patients for whom LAAM seemed well suited do not respond well to either methadone or buprenorphine and stated: *"The return of LAAM to our treatment armamentarium would be likely to bring a significant number of these patients back into treatment and to help them to return to a productive life."*

In 2011, the FDA granted the requested determination maintaining LAAM as an Approved Drug Product, consequently allowing it to be marketed as a generic drug.

Prior to and subsequent to these regulatory decisions, a number of studies reported that LAAM was superior to methadone in reducing urine specimens positive for illicit opiates, incarcerations, and sometimes patient retention and satisfaction. If LAAM is better than either methadone or buprenorphine in appropriate patients, why isn't it available? Even the uncommon instances of Q-T prolongation and even rarer instances of TdP associated with both methadone and LAAM can be reduced or prevented with appropriate screening and ECG monitoring.

In the US there is no incentive for a pharmaceutical company to take on the costs associated with submitting an application and manufacturing a product which may be superior for many patients but might reduce provider income. Even if it were successful enough to begin to recover development costs it would be subject to immediate generic copies before those costs were fully recovered. In the EU there is no incentive for a pharmaceutical company to take on even more costly analysis and perhaps new studies to counter the CPMP recommendation to the EMA.

Meanwhile, in much of the developing world where daily access to treatment clinics or pharmacies is often prevented by distance and restricted transportation infrastructure, LAAM, with proper staff training, could provide effective treatment at moderate cost. However, regulatory agencies are reluctant to approve use of a product that is either unavailable or not widely used in Europe or the US, or that has a "tainted" reputation, even if that reputation is undeserved. There should be a better way.

\* EMA= European Medicines Agency; CPMP= Committee for Proprietary Medicinal Products

## Upcoming Events in HIV/AIDS, Public Health and STI

Name	Location	Date	Abstract	Scholarships
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			<b>Deadline</b>	
Conference on Retroviruses and Opportunistic Infections (CROI)	<b>Boston MA, USA</b>	Feb 22-25, 2016	Sept 30, 2015 Late-breaker: Jan 5, 2016	Yes
18 <sup>th</sup> Congress of the European Society for Sexual Medicine (ESSM)	<b>Madrid, Spain</b>	Feb 4 – Feb 6, 2016	Closed: Oct 15, 2015	Yes (travel award)
17th International Congress on Infectious Diseases (ICID)	<b>Hyderabad, India</b>	Mar 2-5, 2016	Closed: Nov 1, 2015	No
12 <sup>th</sup> International Congress on AIDS in Asia and the Pacific	<b>Dhaka, Bangladesh</b>	March 12-14, 2016	Postponed from 20-23 November 2015	?
7 <sup>th</sup> Academic and Health Policy Conference on Correctional Health	<b>Baltimore, Maryland, USA</b>	Mar 17-18, 2016	Closed Sept. 29, 2015	Yes
International Conference on Urban Health	<b>San Francisco, California</b>	Apr 1-4, 2016	Dec 8, 2015	?
Southern African HIV Clinicians Society Conference	<b>Johannesburg, South Africa</b>	Apr 13-16, 2016	Closed: Oct 30, 2015	No
International Conference on Antiviral Research	<b>La Jolla, CA, USA</b>	Apr 17-21, 2016	Jan 15, 2016	No
HIV Drug Therapy in the Americas	<b>Mexico City, Mexico</b>	Apr 28-30, 2016	Feb 1, 2016	No
Canadian Association for HIV Research (CAHR)	<b>Winnipeg, MB</b>	May 12-15, 2016	Jan 13, 2016	Yes
International Symposium HIV & Emerging Infectious Diseases (ISHEID)	<b>Marseille, France</b>	May 25-27, 2016	Feb 1, 2016	?
Canadian Public Health Association Conference	<b>Toronto ON</b>	Jun 13-16, 2016	Closed: Nov 19, 2015	?
7th Conference on Peer Education, Sexuality, HIV & AIDS	<b>Nairobi, Kenya</b>	June 15 – 17, 2016	Feb 29, 2016	No
International Conference on HIV Treatment and Prevention Adherence	<b>Miami, FL USA</b>	June 2016?	TBD	No
Society for Epidemiologic Research: Epidemiology Congress of the Americas	<b>Miami, FL, USA</b>	June 21-24, 2016	Closed: Nov 2, 2015	Yes (travel awards available)
Towards an HIV Cure Symposium	<b>Durban, South Africa</b>	July 16-17, 2016	Feb 4, 2016	Yes (use the AIDS 2016 scholarship application system)
International Aids Conference (AIDS 2016)	<b>Durban, South Africa</b>	July 17 – 22, 2016	Feb 4, 2016	Yes
International Harm Reduction Conference	<b>TBD</b>	Oct 2016?	TBD	TBD
HIV Drug Therapy	<b>Glasgow, UK</b>	Oct 23-26, 2016	July 8, 2016	Yes
American Public Health Association Meeting	<b>Denver, Colorado</b>	Oct 29- Nov 2, 2016	Feb 22, 2016	?

Australasian HIV/AIDS Conference	<b>Adelaide, Australia</b>	Nov 14-16, 2016	TBD	TBD
National HIV Prevention Conference (NHPC)	<b>TBD</b>	Dec 2016?	TBD	TBD

**Newsletter Editorial Board :**

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