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Proposition 65 - Request for Comments on the **Chemicals The State Proposes to List as "Known to Cause Cancer" (Carcinogens) - Zidovudine (AZT)** by the Labor Code Mechanism¹

Dear Drs. Denton and Roland:

These comments are submitted on behalf of the San Francisco AIDS Foundation, the Gay and Lesbian Medical Association and myself to both of your agencies. ² We request that you act together in the interest of public health and that OEHHA halt its potentially harmful proposal to list and identify AZT as a chemical the State of California "*knows to cause cancer*" under Proposition 65. Such

¹ Health and Safety Code Section 25249.5 et seq. - Proposition 65
http://www.oehha.org/prop65/docs_admin/LCCIC061209.html

² We do not represent any person regulated by Proposition 65. For the last several years, the contact person organized public comment on OEHHA's previous considerations of AZT, advocating on behalf of patient groups and HIV service organizations.

an action will be harmful to persons infected with or at risk of infection by HIV, the virus that causes AIDS. It will convey the public message from State health officials that this drug is as dangerous as benzene or asbestos (which are also listed) and without significant medical benefit. Ordinarily, Proposition 65 allows its cancer messages for pharmaceuticals to be explained by doctors so as to avoid enforcement. In this case, we worry about those many vulnerable people trying to

Unlike conditions for other illnesses, HIV/AIDS patients, suffer from dangerous levels of stigma and discrimination documented to result in delayed medical care or scaring patients away from doctors altogether. The longer the delay, the worse progress in disease. In some countries a woman will be violently beaten by her partner if she even tries to determine her own HIV status or asks her partner to get an HIV test. Going to a clinic for actual treatment is even scarier.

cope with HIV who will be scared away by the Agency's action or lack resources to get their health warnings where they should - from a qualified physician in a good healthcare setting.

Instead the reaction to the State's finding will be to exacerbate the fear,

stigma and other causes uniquely characteristic of this disease that keep these patients away from good care and that delay life saving treatment or means of prevention. The harm will not be limited to our state borders. Just as OEHHA adopts the pronouncements of international authorities – as it does now in this action – to accomplish its hazard identification, non-US health ministries and others where a long history of quack campaigns against AIDS therapies has caused great hardship will look to what OEHHA says.

This request for concerted, joint agency action is critical to address the legal pressures OEHHA believes that it is under, erroneously in our view, with regard to

AZT is the first drug approved by FDA to treat HIV/AIDS and to prevent HIV transmission from mother to child. In a landmark 1994 study, the drug was shown to prevent HIV transmission from mother to fetus by 67%. Along with other practices, HIV infection of newborns has been almost eliminated in this country using this drug. Not so in the developing world where the virus is uncontrolled. The UN estimates 370,000 preventable infections occurred last year in children, down from 800,000 in 2000. The only problem was accessing the approved preventions. AZT is an important therapeutic drug against HIV/AIDS in infected adults and children. It also protects against cancers that result when HIV overwhelms natural body defenses. It's the first AIDS drug to go off patent and be available in low cost generic form. We still need it badly.

AZT and Proposition 65. OEHHA has other options than its current proposal with regard to AZT that will blunt the adverse consequences to public health if it proceeds as planned. Several times over the last 10 years when AZT has been reviewed before, the following request was made to mitigate harm caused by an unedited listing: a regulatory

annotated listing 1) directing persons to consult a physician, 2) that this drug has significant benefits with its approved uses recommended by all authorities after evaluating its risks, and 3) that its risks are equivocal and closely monitored. The drug is best not listed at all as previous submittals by several HIV service organizations, the U.S. FDA, clinical trial researchers and others have explained to OEHHA.

Joint agency consideration of the best course of action makes even more sense today during the State's budget crisis. One of the proposals before the Legislature is to eliminate OEHHA entirely and fold all of its functions into the Department of Public Health.³ If OEHHA were to act inconsiderately or independently during this time of financial and organizational uncertainty, it runs the risk of taking steps that cause harm but with no operational means to fix them later. The State Office of AIDS is the agency best suited to apprise the public of risks and benefits from AZT use.

These requests can be accommodated entirely despite OEHHA's untested view that recent court actions about the "Labor Code" mechanism direct an automatic listing of AZT as a "ministerial duty." A ministerial duty is one the entity is required to perform in a prescribed manner without any exercise of judgment or opinion concerning the propriety of the act.⁴ But OEHHA has often shown that the forms of its listings are not subject to prescribed manners. It frequently restricts, qualifies and alters the form or name of a chemical that the Labor Code authorities –IARC or NTP – nominated. Whether those restrictions were done under another mechanism or not is immaterial. The form of listing is not prescribed even if the listing itself turns out to be. The lower court reviewing these issues made no pronouncements about the manner of listing, only the duty to develop *some* automatic list.

Every drug has risks. It has long been known that AZT given to rodents in doses many times greater than prescribed for humans produces tumors in rodent pups. Although animals often serve as "canaries in coal mines" about these problems, in this case scientists believe the rodents are built differently and the results may not point to human risk. Over fifteen years of closely monitoring widespread human use of AZT – the standard of study for how people really respond - shows no evidence so far that the chemical causes cancer in humans.

These comments explain how to accommodate those concerns. The recent decisions of a superior court on the ministerial duty are without statewide effect, actively under appeal and without the force of an order directing immediate agency action. Even if a ministerial duty to

list existed, OEHHA has free reign to exercise its other authorities - as it has many

³ http://www.dof.ca.gov/budget/historical/2009-10/may_revision/documents/May_Revision_2009-10_General_Fund_Proposals.pdf

⁴ US Ecology v Calif 92 Cal app 4th 113

times in the past – to qualify, restrict or elucidate the content of listing for an individual chemical under the Labor Code mechanism. Failure to do so now when the public’s health is at stake will raise serious objections to OEHHA’s methods and call into question the validity or status of other chemicals such as Vitamin A, (Retinol), aspirin or industrial chemicals such as silica, qualified by regulatory annotation.

It will be viewed as arbitrary and inexplicable, for example, that OEHHA took pains to explain to women directly the benefit from Vitamin A or to be on guard against risks of aspirin during pregnancy and to refuse to craft the proper public message in the case of this important drug which could save their own lives and that of their unborn children or the lives of other vulnerable patients. Listing by means of the Labor Code is no barrier to this responsible administrative function to annotate demanded of a public health agency.

An additional legislative determination interferes specifically with use of a ministerial duty to list the chemical. A more specific provision of the Health and Health Safety Code takes precedence over the general terms of Proposition 65. California law singles out AZT by name. The Code records that:

The Legislature hereby finds and declares all of the following: (a) State-of-art knowledge regarding treatment of people infected with the human immunodeficiency virus (HIV) indicates that **active HIV infection (AIDS) can be a manageable, though chronic, condition with the use of drugs such as zidovudine (AZT).... AIDS experts across the nation agree that early intervention with these drugs can prolong life, [and] minimize the occurrence of more serious illnesses....** (b) For reasons of compassion and cost effectiveness, **the State of California has a compelling interest in ensuring that its citizens infected with the HIV virus have access to these drugs.** Health and Safety Code sec. 120950, emphasis added.

The safety of AZT is a statutory determination. The Code also states that the legislature “finds and declares ...AZT improves and prolongs the quality of life for those suffering from AIDS [and] is believed to reduce the infectiousness of a person infected with human immunodeficiency virus (HIV).” [Health and Safety Code Sec. 120925]. In light of these specific pronouncements, a ministerial duty by agency action could not be used to frustrate the statutorily described compelling interests of recommended uses for this drug.

The administrative record documenting the scientific basis not to list AZT after reviewing all relevant studies is well known to OEHHA. We attach here a selection from that record. But the entire volume of submittals to OEHHA about AZT from state AIDS organizations, by Dr. James Oleske (investigator for the landmark study of AZT), FDA, and others is incorporated here by reference and made part of these comments. It is unfortunate OEHHA has cutoff discussion of this important scientific material in its notice. The situation and the untested rules of Proposition

65 demand a full appreciation of the consequences for the Agency's actions. If this is indeed the time when the OEHHA will be eliminated, its last acts should not produce a legacy of failed public health messaging.

We request that the Agencies:

- Act jointly, with OA as lead, to evaluate risks and benefits of AZT
- Halt the current proposal to list and identify AZT under Proposition 65 [There is no currently effective duty to list.]
- Not list AZT under Proposition 65. If a listing must proceed, do so only with immediate annotation as described in this letter. Any period of listing without annotation results in harm.

Thank you for considering our requests. Please let us know if you have any questions.

Sincerely,



Robert Reinhard

And on behalf of:

San Francisco AIDS Foundation <http://www.sfaf.org>

Gay and Lesbian Medical Association <http://www.glma.org>

CC: w/attachments

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