

The Decades-Long Universal Disregard of NIOSH Precautions During Handling, Preparing, and Administering the "Hazardous Drug" Lupron (leuprolide)

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Triple G's ??? ... You're Kidding Me!!! --- Get that Stuff AWAY from Me!!!

Would you say "Yes" to a Lupron injection if it was given to you by someone who was required (while handling, preparing, and administering the Lupron injection) to protect themselves by wearing a chemotherapy gown, two pairs of chemotherapy gloves, and chemical safety goggles? (It's easy to hazard a guess that most consumers' reaction to an approaching, Lupron-syringe-toting, gowned, gloved, and goggled entity would be lively variations of a "NO thanks!".)

But gowned, gloved, and goggled is precisely how your RN or MD should have been attired during any Lupron injection. (And the need for this special gear applies equally to parents or loved ones who are handling, preparing, and administering Lupron injections to their loved ones in the home setting).

What follows are some background details - open information that is well documented, yet, most peculiarly, physicians prescribing Lupron and the patients 'accepting' Lupron are completely unaware of this most serious and very relevant information. Please read, share, spread awareness, and demand compliance to these precautions ...

Since its initial approval by the FDA in 1985, Lupron has been classified as "chemotherapy", an "antineoplastic", and a "hazardous drug". Lupron (leuprolide) is categorized as a "hazardous drug" according to NIH (National Institutes of Health), [OSHA](#) (Occupational Safety and Health Administration), and the Material Safety Data Sheets ([MSDS](#)).

Material Safety Data Sheets, "MSDS", are documents that are required (in accordance to codified regulations - [29 CFR 1910.1200](#)) to be present at all premises containing hazardous drugs, and are manufacturer summaries of the drug/chemicals' properties and hazards. The MSDS identifies specific methods of personal protection employees should use to prevent occupational exposure to hazardous substances.

Lupron's 1990 MSDS (section 'Special Protection Information') lists the use of [rubber gloves and goggles](#) as protective gear for healthcare workers to employ when handling the hazardous drug Lupron. Note in a more recent Lupron MSDS (advising [protective gloves and chemical safety goggles](#)) the procedure to be followed in the case of a Lupron (leuprolide) leak or spill is to ... "evacuate area".

In 1999, OSHA's 'Technical Manual' listed [Lupron as a "hazardous drug" and an "antineoplastic"](#), and detailed specific precautions healthcare workers should use to protect themselves from occupational exposure. Beginning in 2000, NIOSH (National Institute for Occupational Safety and Health) "[began working with multiple partners and stakeholders to address the issue](#) of occupational exposure to hazardous drugs". This led to an "Alert" published by NIOSH in [2004, Publication # 2004-165](#) (entitled "Preventing Occupational Exposure to Antineoplastics and Other Hazardous Drugs in Health Care

Settings"), identifying "a sample [list of major hazardous drugs](#)", and "leuprolide [Lupron], an antineoplastic" remained on the list.

As delineated in this NIOSH [2004 Alert](#) (as well as in [subsequent NIOSH lists](#)), leuprolide (Lupron) has been included on this "hazardous drug" list because of its "carcinogenicity, teratogenicity (reproductive and developmental toxicity), and genotoxicity" (see pages 32, 37). And as also stated in this "Alert" (and subsequent NIOSH lists): "When a drug has been judged to be hazardous, **the various precautions outlined in this Alert should be applied when handling that drug**" (see page 33) (emphasis mine). This 2004 "Alert" also states: "The OSHA hazard communication [standard requires hazardous drugs to be handled with the use of special precautions](#). The mandate applies not only to health care professionals who provide direct patient care but also to others who support patient care by participating in product acquisition, storage, transportation, housekeeping, and waste disposal."

The very first page of [the 2004 NIOSH "Alert"](#) stated: "NIOSH requests that employers, editors of trade journals, safety and health officials, and unions bring the recommendations in this Alert to the attention of all workers who are at risk." Since 2004, there have been [three additional reviews](#) by NIOSH of drugs listed as hazardous (in [2010](#), [2012](#), and [2014](#)), and Lupron/leuprolide remains on the list (and other GnRHs are on this "hazardous drug" list as well, i.e., goserelin and triptorelin).

As in previous (and subsequent) years, this [2004 NIOSH "Alert"](#) identifies that healthcare workers should, ***when preparing*** a hazardous drug such as Lupron, "**wear protective gloves and gowns if [] opening drug packaging, handling vials ...**"; and ***when administering*** a hazardous drug such as Lupron, healthcare workers should "**wear double gloves, goggles, and protective gowns**" and "**bag [all used gear] in the yellow chemotherapy waste container**" (emphasis mine).

The 2004 NIOSH "Alert" addressed conditions for exposure to hazardous drugs, including "***expelling air from syringes filled with hazardous drugs, [and] administering hazardous drugs by intramuscular and subcutaneous routes***" (emphasis mine). These are the ***very*** conditions that exist in home handling, home preparation and home administration of Lupron, and these home maneuvers occur in the exact same manner as they do in the clinical setting. (Various Lupron labels provide patient and parental instructions to "[advance the plunger to expel the air from syringe ...](#)" [see p. 25]) This writer has heard from parents who injected daily subcutaneous Lupron and monthly intramuscular Lupron Depot into their child, and "expell[ed] air from syringes". None were told Lupron is a hazardous drug that requires special precautions and protective gear during its handling, preparation and administration.

The American Hospital Formulary Service's 1999 'Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs' advised any healthcare worker planning on conceiving or fathering a child to avoid handling the hazardous drug at least 3 months prior to conception attempts.¹ More recent guidelines of the American Society of Health-System Pharmacists state "[b]ecause reproductive risks have been associated with exposure to hazardous drugs, [alternative duty should be offered](#) to individuals who are pregnant, breast-feeding, or attempting to conceive or father a child."

While NIOSH's mission is dedicated to protecting healthcare workers from occupational exposure to hazardous drugs (encompassing workers in various healthcare settings, including home health care agencies), it is only healthcare workers that are addressed. The consumer in the home setting who is

¹ American Hospital Formulary Service. AHFS Drug Information 1999. ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs. p. 1030/1.

independently handling, preparing and administering Lupron to their self or their child or a significant other remains outside of the NIOSH mission. (Who *is* protecting this consumer?)

In addition to parental preparation and administration of subcutaneous and intramuscular Lupron injections in the home for early or precocious puberty and/or short stature, there are other conditions where a consumer either self-injects Lupron, injects Lupron into a loved one, or has a loved one inject Lupron into themselves: i.e., pre-teens and teens prescribed intramuscular [Lupron injections for gender dysphoria](#), young and middle-age women prescribed subcutaneous [Lupron injections for ovulation induction](#) for in vitro fertilization (IVF) cycles, or for egg donation, or surrogacy --- and, prevalent in the past, were prostate cancer patients prescribed daily subcutaneous Lupron, as well as women with endometriosis prescribed daily subcutaneous Lupron. None were ever told Lupron is a hazardous drug that requires protective gear during its handling, preparation and administration.

Moreover, this writer has never once (in 27 years of closely following this issue) worked with, met, or heard of an RN or MD who was gowned, double gloved, and goggled when handling, preparing and administering Lupron; and likewise have never heard from, heard of, or read about any patient who received a Lupron injection from an RN or MD who was gowned, double gloved, and goggled. Thus it would incredulously appear that despite the best intentions of NIOSH, not one healthcare worker handling, preparing, and administering Lupron has been alerted (or compliant) to the mandate for special precautions and protective gear. The 2004 NIOSH "Alert" does acknowledge "[g]uidelines have been established for handling hazardous drugs, but adherence to these guidelines has been reported to be sporadic." Of note, in 2000 this writer mailed a small pilot survey to random U.S. hospitals enquiring of their policy and procedure for the administration of Lupron: 100% of respondents reported they had "no policy or procedure for the administration of Lupron/leuprolide". ²

Patients, parents and significant others have been instructed on 'how' to inject Lupron/leuprolide into themselves, their child, or significant other, but they have **not** been informed of the need for special precautions and the need for protective gear. A prescription for Lupron (or other GnRHs) should be accompanied by a consent form explaining the above detailed NIOSH definitions, mandates, and guidelines; and this consent form should specifically list the **required** protective gear the patient, parent or significant other will need to possess **prior to** (or along with) filling the prescription --- i.e., chemotherapy gloves, chemotherapy gowns, chemical safety goggles, and a chemotherapy waste container. Instructions should also be provided regarding the proper disposal of the chemotherapy waste containers.

Lupron has been routinely used **for decades** by, to name a few, the Gyn, RE, urologic, and pediatric communities - involving men, women and children of all ages. **How could these august communities, these medical experts, not know** that Lupron is a "hazardous drug" requiring special precautions in its handling, preparation, and administration? Clearly government agency "Alerts" were issued, repeated hazardous drug lists and reviews of special handling precautions were compiled, published and promoted, and NIOSH mandates and guidelines were emphasized - repeatedly and regularly. **How could the medical community not know that Lupron is a hazardous drug requiring special precautions and protective gear???**

In its Lupron labels, the manufacturer fails to identify Lupron as a "hazardous drug" requiring special precautions during handling, preparation, and administration. In the label's "Contraindications"

² Unpublished data

section, it is identified that Lupron may be "a potential hazard to fetus", but otherwise no mention of Lupron's "hazardous" status is revealed to the consumer. For example, the "Warnings" and "Precautions" section of Lupron labels are completely devoid of any warnings or precautions about Lupron's "hazardous drug" status or the requirements for special precautions during its handling, preparation, and administration ([see pgs. 2, 10, 21, 31, & 41 for each of the various dosages and formulations](#)).

It is most interesting to note the changes, stratagems, devices and dodges that occur in Lupron's label as time went by. (And for purposes here, label information which pertains only to Lupron's hazardous status is provided.) In summary, the following details are provided from various Lupron labels:

- 1985 and shortly thereafter: Lupron's label (prostate cancer) contained "Directions for Using Lupron" and "Some Special Advice" - neither of which mention Lupron's hazardous status and need for special precautions in handling, preparation, and administration. The "Warnings" and "Precautions" sections of the label contained no mention of Lupron's hazardous status. These early labels did state "A waste area is provided in the LUPRON Patient Administration Kit [for used syringes]." (i.e., see 1986 Physicians' Desk Reference [PDR] for "Lupron").

- By 1992, Lupron's label (endometriosis) contained new information. The "Contraindications" section contained a report of an "anaphylactic reaction", with a footnote (#1) inserted into the text. At the end of the label, a new section was added, "Reference", in which the citation for aforementioned footnote #1 was listed. The "Warnings" and "Precautions" sections of the label continued to contain no mention of Lupron's hazardous status. (i.e., see 1992 PDR for "Lupron Depot").

- By 2007, [Lupron's label \(multiple indications\)](#), in the "Contraindications" section, identified two new reports of "anaphylactic reactions"; and now there were two footnotes inserted into the text (#1 and #2). The "Reference" section was changed to read "References", and the two citations for footnotes #1 and #2 were listed in "References". The "Warnings" and "Precautions" sections of the label continued to contain no mention of Lupron's hazardous status.

- But in [2008, Lupron labels](#) (multiple indications) displayed a disturbing sleight of hand, which continues through [current labels](#). The "Warnings" and "Precautions" sections, or any other section, of the label continue to contain no mention of Lupron's hazardous status. Newly worded information on "symptoms consistent with an anaphylactoid or asthmatic process" was now located in the "Warnings" and "Post-Marketing" section (and no longer in "Contraindications"), and, significantly, **the previously inserted footnotes which had been used to reference the anaphylaxis reports were now removed from the text of the label. *There are no footnotes whatsoever in the entire Lupron label.*** But, cleverly, as if hiding evidence in plain sight, the "References" section of the label remains in place, and this "References" section now contains 4 citations. However, there are **no corresponding footnotes within the text** for any one of the 4 citations listed in the label's "References" section.

The 4 new citations in the "References" section are as follows: (#1) the 2004 NIOSH Alert, (#2) 1999 OSHA Technical Manual on hazardous drugs, (#3) 2006 ASHP guidelines on hazardous drugs, and (#4) 2005 Oncology Nursing guidelines on hazardous drugs (see [pgs. 6, 14, 25, 36, 47](#)). ***Again, most curiously, not one of these 4 citations/"References" -- or the information the citation source contains -- are referred to, mentioned, identified, or discussed, at all, within the Lupron label.***

And it is entirely possible that this "References" section (located at the end of the label) ***may never be read or even noticed by the consumer***, who undoubtedly would focus upon the label's "clinical pharmacology", "metabolism", "excretion", "clinical studies", "contraindications", "warnings", "precautions", "adverse reactions" and "post-marketing" sections. And even if a consumer did read the few words within the citations in the "References" section, the significance and implications of these citations may not be readily apparent.

However, if the consumer (or prescriber) *were to notice* the "References" section ***and proactively pursue, obtain, and read the sources for these 4 citations***, then the consumer (and prescriber) would indeed realize that Lupron is a "hazardous drug" requiring special precautions in its handling, preparation, and administration.

Per FDA definitions, the ["References" section in a drug label](#) "may contain references when prescription drug labeling must summarize or otherwise relay on a recommendation by an authoritative scientific body, or on a standardized methodology, scale, or technique, ***because the information is important*** to prescribing decisions" (emphasis mine). To secrete this "important information" only within a few references (inserted inconspicuously at the end of label, tucked away where the consumer is least apt to read), without any related and footnoted descriptive text, and without ***any*** mention of the significance of the information contained within the 4 authoritative scientific bodies cited within "References", is peculiar, deceptive, alarming and unacceptable - to say the least. Sneaky, shifty, and slippery are also a few other adjectives that come to mind.

It is the duty of the physician prescribing Lupron/GnRHs, or any drug, to inform patients and/or parents of a drug's known risks. The implications, and ramifications, of the past thirty-plus-year scenario in which physicians have been either oblivious, indifferent or in denial of Lupron's hazardous status, is a discussion beyond the scope of this paper (*and* beyond the pale) - but speaks to a very troubling issue. Ethically speaking, without being informed of Lupron's hazardous status and the requirements of special precautions and need for protective gear during its handling, preparation and administration, the patient/parent/significant other has been deceived, put at unnecessary risk and placed in danger, denied their right to accurate information and informed consent, and have been subject to blatant human experimentation for which they remain totally unaware.

As Aldous Huxley said "Facts don't cease to exist just because they are ignored." That Lupron is a known "hazardous drug" requiring special handling precautions and protective gear during handling, preparation and administration, are manifestly relevant and ***hugely*** significant facts that have been ignored long enough.