minority-opinion/)

One-Dose Doxy (https://www.lymedisease.org/members/lyme-times/special-issues/tick-borne-disease/one-dose-doxycycline/)

Overview of the Tick-Borne Disease Working Group: What Has Been Accomplished so Far? (https://www.lymedisease.org/members/lyme-times/special-issues/tick-borne-disease/tick-borne-disease-working-group-overview/)

TICK-BORNE DISEASE WORKING GROUP
SPECIAL ISSUE
(HTTPS://WWW.LYMEDISEASE.ORG/MEMBERS/LYME-TIMES/SPECIAL-ISSUES/TICK-BORNE-DISEASE/ )

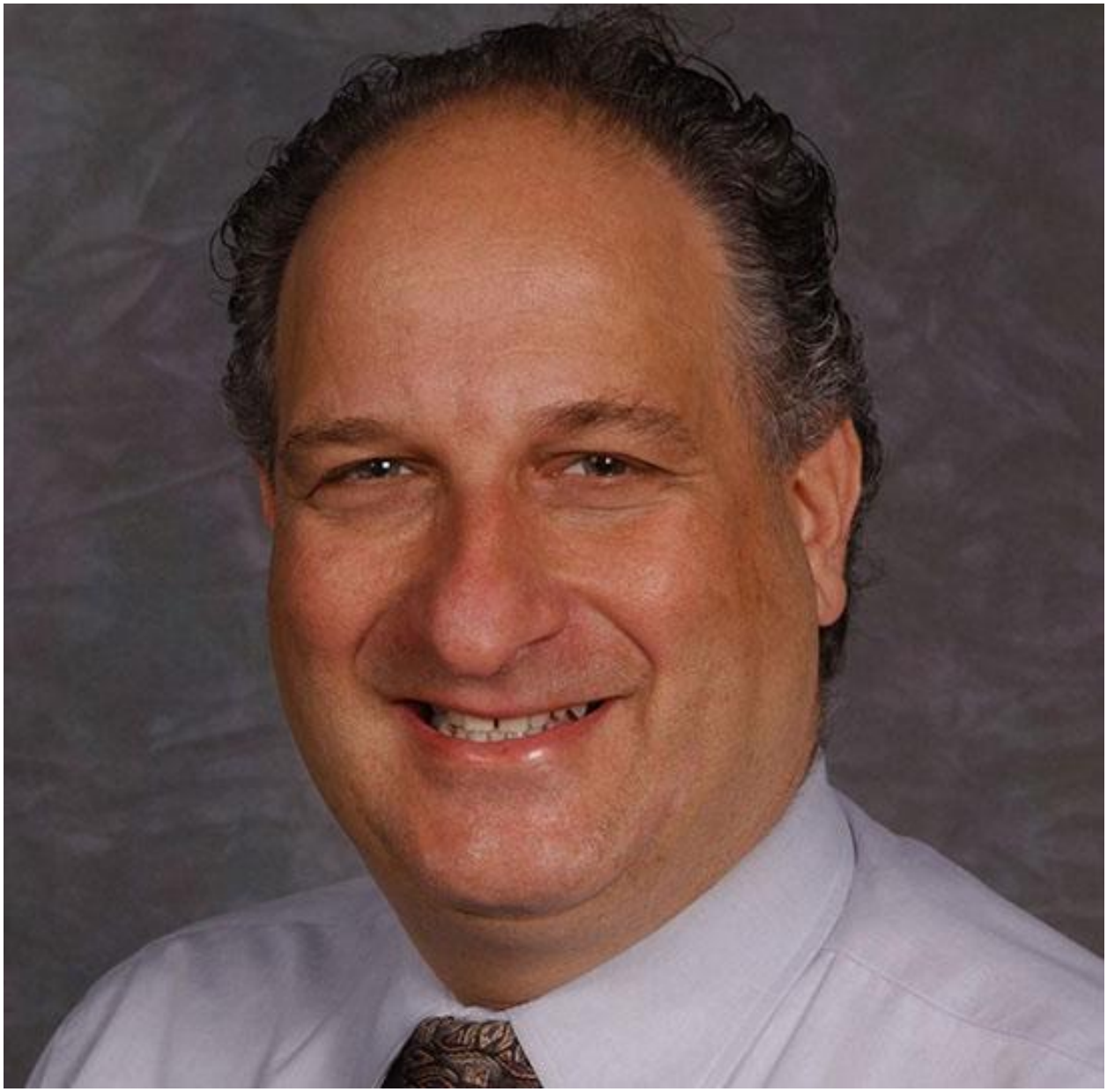
# How the LYMErix Lyme Disease Vaccine was Pulled from the Market

*Patricia Smith, president of LDA, identifies lessons we can learn from the LYMErix Lyme disease vaccine story and pitfalls we can hopefully avoid in the future.*

By Pat Smith

## Present-Day Lyme Vaccine

Fast-forward to the present. There is a new vaccine that has just completed Phase I/II trials in Germany and Austria. It is OspA-based, uses more than one strain of the bacteria (U.S. plus European), and, we have been told, the portion of the OspA that invoked the mimicry that started the arthritis cascade (which SKB has never publicly acknowledged occurred from vaccination) has been modified to prevent that occurrence. The manufacturer is Baxter.



According to one of the vaccine's developers, Dr. Benjamin Luft, Stony Brook University, "The results of the clinical trial conducted by Baxter are promising because the vaccine generated a potent human immune reaction, covered the complete range of borrelia active in the entire Northern hemisphere and produced no major side effects. We hope that a larger-scale Phase 3 trial will demonstrate not only a strong immune response but true efficacy in a large population that illustrates protection against Lyme disease."

## Concerns Still Remain About A Lyme Vaccine

LDA understands the value of a vaccine for Lyme disease. However, we should and do have concerns related partly to the fact there is no reliable test for Lyme disease yet, almost 40 years into the identification of the disease, nor is there one that determines active infection.

*How can an individual poised to receive the vaccine determine if they have a Lyme infection already, which, in light of questions raised from the prior vaccine, could possibly prove dangerous to these individuals*

Additionally, there have been published reports of cognitive difficulty and neuropathy including chronic inflammatory demyelinating polyneuropathy (CIDP) in LV patients. This issue also needs addressing in relation to the new vaccine.[5,6]

## Questions Need To Be Fully Explored

Questions related to the safety and efficacy of the prior vaccine do not appear to have been fully explored nor answered, but have been met publicly instead with blame being laid at the door of the Lyme community for failure of the first vaccine. In this climate, it is not really a surprise that Lyme patients and the public are concerned about a new rollout. Before that occurs, we recommend the following:

- All the final reports/studies/research from the past vaccine, LV, need to be made public so concerned individuals can evaluate coverage of issues and corresponding analyses.
- All of the safety and efficacy issues identified as problematic, unless proven to be false or insignificant rather than not being definitively or clearly established, regarding the past vaccine need to be conclusively addressed in relation to the new vaccine. Claims of the effectiveness of changes from the previous to the new OspA vaccine in remedying safety concerns need to be scrutinized and verified.
- More comprehensive and determinative research than was done for the previously approved Lyme vaccine needs to be done prior to approval on safety and efficacy.

- Coordinated vaccine education programs need to be developed for healthcare providers and vaccine recipients or legal guardians of recipients. The importance of and mechanisms for adverse event reporting need to be included in education programs, as past LV recipients reported being dismissed by providers and/or the manufacturer and were unaware of the ability to self-report to VAERS.
- Significant outreach to and education of healthcare providers needs to occur prior to rollout.
- Listing of adverse events in label contraindications and the VAERS table of reportable events must be seriously protective of vaccine consumers.
- Safety, immunogenicity, and efficacy of the Lyme disease vaccine in children need to be demonstrated if the vaccine is recommended for them.
- All panels that review the vaccine need to be as free as possible of professional and financial conflicts of interest—as should always be the case.

## Food for Thought

"During the past thirty years, vaccines have experienced a renaissance. Advances in science, business, and distribution have transformed the field to the point where vaccines are recognized as a "best buy" in global health, a driver of pharmaceutical industry growth, and a key instrument of international development."[7]

While these are all positive outcomes, this statement by an official of the past producer of the only Lyme vaccine ever approved clearly reinforces the reality that vaccines are big business, and that all stakeholders — including regulators, advisors, healthcare providers, consumers, and advocates — would be derelict if we were not vigilant in ensuring that business objectives do not preempt the goals of public health or the rights of consumers.

## References:

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*Editor's note: Any medical information included is based on a personal experience. For questions or concerns regarding health, please consult a doctor or medical professional.*