

REQUEST TO MAKE A BRIEF COMMENT ON OCTOBER 11, 2006 at the FDA
Regarding Rule for Exception to Informed Consent

Submitted by:

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for Counter-terrorism; and the *Dallas Metropolitan BioTel (EMS) System*

Summary Points

- Because of inaction of the medical community at large in terms of performing methodical, evidence-based quality assurance, the rights of hundreds of thousands of Americans, including children and young adults have been denied
- MANY of the widely-accepted, but empiric, standards of care that we have used for cardiac arrest and trauma have now been proven to actually be harmful by intrepid scientists who persevered in implementing clinical trials (despite the intimidating roadblocks)
- Those dedicated health professionals and stewards of the public trust have spared hundreds of thousands of American lives from empirically-developed patient care plans
- This concern does not even address the need to conduct proactive clinical trials for new life-saving innovations, even of those that are already FDA-approved for use but not yet validated in large clinical trials
- Many of these interventions, around for more than a decade, are ready for widespread national dissemination pending clinical trials
- In the meantime, millions of American families will have a tragic and *needless* loss of their love ones because of the impasse
- In addition to these comments, the proposed speaker will provide some recommendations for achieving effective community consultation that achieve full public support without any protest

STATEMENT:

Defending the Rights of All Individuals

Severe traumatic injury is the number one killer of American children and adults < 45 years of age affecting tens of thousands of U.S. citizens annually. Also, for every death, there are four more left with permanent disability, meaning that, each year, hundreds of thousands nationwide would be affected by early interventions that could alter outcomes following severe injury. Yet, despite the tremendous burden on the national economy and the staggering impact on adjusted years of productive life across the U.S. (and worldwide as well), only a handful of clinical trials have been conducted in the preoperative resuscitative phase of care, a pivotal turning point during which many of the final outcomes are determined. More strikingly is the fact that, among those very small numbers of trials that have been conducted, several actually demonstrated not only the ineffectiveness, but often the detriment, of what had been empiric (yet widely-accepted) standards of care. Though they were not proactive breakthroughs of promising new therapies, even these "negative" clinical trials have, as a result now saved thousands of lives because they challenged empiric therapies. And most concerning is the concern that, to date, the evidence for preoperative interventions that truly change the outcome of severe trauma victims is clearly lacking.

Likewise, despite truly compelling studies that demonstrate the incredibly high potential for reversibility of certain death for the tens of thousands of Americans who experience lethal out-of-hospital ventricular dysrhythmias, very few clinical trials have been conducted, even those implemented to prove or disprove current standards of care, let alone promising new interventions. The concept of methodical investigation of new life-saving therapies, even those not considered experimental in nature (ie, those which are already FDA-approved), has virtually come to a standstill in America, a tragic disservice to millions of affected American families who are have the reasonable expectation that the medical community is doing everything possible to ensure the best possible care for their loved ones when an unexpected life-threatening emergency strikes.

The gridlock has been largely due to political pressures that have emanated, understandably, from concerns over the protection of an individual's right to consent to treatment along with unfaded memories of secretive human experimentation, ranging from Dachau to Tuskegee.

At the same time, on a day-to-day basis, most Americans are completely unaware of the treatments that they will receive if they, through some misfortune, suddenly require immediate prehospital resuscitative care whereas a clinical trial brings such protocols to the public. Also, those that gain the most from prehospital clinical trials those from minority and underserved populations.

On a daily basis, critically ill and injured patients receive a myriad of therapies under the principle of implied consent. Ironically, due to a lack of clinical trials, the interventions provided may vary widely depending on the individual judgment on any given day of the particular provider whom the patients inherit at the time of their unanticipated emergency. While carefully crafted scientific protocols usually lead to more standardized, predictable, prospective treatment plans for than day-to-day care, for reasons stated, if a formal research process is involved, even those studies testing or comparing interventions that are already considered to be standard of care, must undergo rigorous regulatory scrutiny. In turn, this involves expensive and often tedious processes that truly inhibit the impetus to perform the research.

About the Proposed Speaker:

The proposed speaker, represents the U.S. Metropolitan Emergency Medical Services Medical Directors Consortium (aka, the *Eagles Coalition*), the organization comprised of the medical directors for the FBI, *U.S. Secret Service*, *White House Medical Unit* and most of the jurisdictional medical directors of the 9-1-1 (EMS) systems for the 30 largest cities in the U.S. The speaker is an internationally-recognized veteran investigator who has conducted more than a dozen successful clinical trials involving exception to informed consent since the early 1980s in EMS systems ranging from Seattle, Houston and now Dallas. He has also published classic state-of-the-art primers on how to successfully design and implement controlled clinical trials in the out-of-hospital setting.

Utilizing scrupulous community consultation procedures, a concept that later became a model for FDA and its subsequent rules for exception to informed consent, he has achieved a tremendous track record in terms of conducting well-publicized, universally-accepted clinical trials for cardiac arrest and trauma.

As a Co-Principal Investigator for the multi-center *National Institutes of Health* (NIH) Resuscitation Outcomes Consortium (the "ROC"), established to conduct more than a dozen clinical trials over the next several years, he has performed extensive community consultation (a term he defined in the early 1980's) with essentially universal community acceptance to date. Partnering closely with elected officials, the county medical society, the various news media and emergency care providers, he has re-defined and delineated the most appropriate and productive areas of focus for community disclosure and consultation. The result has been many lives saved with full public support.

As a summary of comments, the consortium believes that the existing rules are more than adequate and that community consultation is a part of study that needs to be funded as a line item in a clinical trial involving emergency and resuscitation interventions. Some other specific comments about the establishment and elements of a community consultation committee will be made as well.

Tinch, Latroy D

From: Crescenzi, Terrie
Sent: Wednesday, September 27, 2006 4:31 PM
To: Tinch, Latroy D
Subject: FW: Emergency Research Public Hearing

Attachments: FDA Comment October 2006.ppt; FDA abstract for October 11, 2006.doc



FDA Comment FDA abstract for
October 2006.ppt (.. October 11, 2...

Latroy,

Here is another submission that will have to go to the docket. This guy already submitted an abstract but apparently revised it and now has also included some slides.

Thanks!

-----Original Message-----

From: Hommel, Carolyn - OC
Sent: Monday, September 25, 2006 10:38 AM
To: Crescenzi, Terrie
Cc: 'paul.pepe@utsouthwestern.edu'
Subject: FW: Emergency Research Public Hearing

Terrie,

I'm forwarding you a copy--he seems to have omitted your e-mail address.

Carolyn

-----Original Message-----

From: Paul Pepe [mailto:Paul.Pepe@UTSouthwestern.edu]
Sent: Monday, September 25, 2006 1:46 AM
To: Hommel, Carolyn - OC; 'paul.pepe@utsw.edu'
Subject: Re: Emergency Research Public Hearing

Terrie:

As requested...

I have attached a slide show * note that the intended "full" talk is the first 52 slides, many of which are just photos or transition slides so that the talk is actually 15 minutes or less.

Much of the intro can be cut, esp if it is redundant from other speakers.. Let me know how it works for you. Note that beyond the first 52 slides there is more stuff at the end. Just ignore them * they are just some others I had from a previous talk

I made a few edits and additions to the "Abstract"

My numbers are 469-323-5480 or 214-616-4839

Thanks, Dr P