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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/19/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/13/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/13/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/11/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/11/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/10/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/05/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/05/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 08/02/2010 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/02/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/31/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/30/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 07/30/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/30/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 07/29/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/28/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/28/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/28/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/23/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/20/2010 |
| EDWARDS LIFESCIENCES | <u>IMR ETLOGIX ANNULOPL</u> | 07/15/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/14/2010 |
| EDWARDS | <u>CARPENTIER-</u> | 07/14/2010 |

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| LIFESCIENCES | <u>MCCARTHY-</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> ANN | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/12/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 07/12/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> ANN | 07/12/2010 |
| EDWARDS LIFESCIENCES | <u>GEOFORM</u> <u>ANNULOPLASTY</u> | 07/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 07/10/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> ANN | 07/06/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> ANN | 07/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 07/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/28/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/24/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 06/24/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 06/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/16/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 06/16/2010 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/16/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/16/2010 |
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| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 06/16/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/15/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/11/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 06/11/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 06/11/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/11/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/11/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 06/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/10/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 06/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/09/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/06/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/05/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 06/05/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 06/05/2010 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/05/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/05/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/05/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/04/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/04/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/04/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/03/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/03/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/02/2010 |
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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/25/2010 |
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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/24/2010 |
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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/24/2010 |
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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/18/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/17/2010 |
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| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 05/13/2010 |

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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 03/30/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/30/2010 |
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| EDWARDS LIFESCIENCES | <u>MC3 TRICUSPID ANNULO</u> | 04/22/2008 |
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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/02/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/02/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/02/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/02/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-</u> <u>MCCARTHY-</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS</u> <u>MYXOMATOUS A</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/01/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 05/01/2008 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE</u> <u>ANNULOPLAST</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE</u> <u>ANNULOPLAST</u> | 04/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/29/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/29/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 04/25/2008 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>MC3 TRICUSPID ANNULO</u> | 04/22/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/17/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/17/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/16/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/09/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/09/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/08/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/08/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/08/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/08/2008 |
| EDWARDS | <u>EDWARDS</u> | 04/08/2008 |

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| LIFESCIENCES | <u>MYXOMATOUS A</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/07/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/07/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS PHY</u> | 04/07/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/04/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/04/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE ANNULOPLAST</u> | 03/28/2008 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 03/27/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/21/2008 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 03/18/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 03/18/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 03/18/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/18/2008 |
| EDWARDS | <u>EDWARD MC3 TRICUSPID</u> | 03/18/2008 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 03/18/2008 |
| EDWARDS LIFESCIENCE | <u>GEOFORM ANNULOPLASTY</u> | 03/17/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 03/17/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/14/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER EDWARDS P</u> | 03/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER EDWARDS P</u> | 03/12/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER EDWARDS P</u> | 03/12/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS GEOFORM MITR</u> | 03/12/2008 |

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| EDWARDS LIFESCIENCES | COSGROVE-EDWARDS ANN | 07/31/2010 |
| EDWARDS LIFESCIENCES | COSGROVE-EDWARDS ANN | 07/30/2010 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS C | 07/30/2010 |
| EDWARDS LIFESCIENCES | EDWARDS MC3 TRICUSPI | 07/30/2010 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS C | 07/29/2010 |
| EDWARDS LIFESCIENCES | COSGROVE-EDWARDS ANN | 07/28/2010 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 07/28/2010 |
| EDWARDS LIFESCIENCES | EDWARDS MC3 TRICUSPI | 07/28/2010 |
| EDWARDS LIFESCIENCES | COSGROVE-EDWARDS ANN | 07/28/2010 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 07/24/2010 |

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| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 05/24/2011 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 05/18/2011 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 05/18/2011 |
| EDWARDS LIFESCIENCES | EDWARDS MC3 TRICUSPI | 05/18/2011 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 05/17/2011 |
| EDWARDS LIFESCIENCES | EDWARDS MC3 TRICUSPI | 05/17/2011 |
| EDWARDS LIFESCIENCES | EDWARDS MC3 TRICUSPI | 05/13/2011 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 05/11/2011 |
| EDWARDS LIFESCIENCES | CARPENTIER-MCCARTHY- | 05/07/2011 |
| EDWARDS LIFESCIENCES | CARPENTIER-EDWARDS P | 05/06/2011 |
| EDWARDS LIFESCIENCES | EDWARDS MC3 TRICUSPI | 05/05/2011 |
| EDWARDS | GEOFORM | 05/03/2011 |

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| LIFESCIENCES | <u>ANNULOPLASTY</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 05/02/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/01/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/01/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/29/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/29/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/29/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 04/29/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/23/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/23/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/23/2011 |
| EDWARDS LIFESCIENCES | <u>CROSGROVE-EDWARDS AN</u> | 04/22/2011 |
| EDWARDS LIFESCIENCES | <u>CROSGROVE-EDWARDS AN</u> | 04/22/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/22/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 04/22/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/21/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/21/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 04/21/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 04/21/2011 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 04/21/2011 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/21/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 04/11/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/31/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/31/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 03/31/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS® AN</u> | 03/25/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 03/25/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/24/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/24/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 03/24/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 03/14/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 03/11/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/11/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/10/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/04/2011 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 02/25/2011 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/25/2011 |
| EDWARDS LIFESCIENCES | <u>IMR ETLOGIX₂ MITRAL</u> | 02/25/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 02/22/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/19/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 02/19/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/19/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/16/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/11/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/11/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/10/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/10/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/10/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/07/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/03/2011 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 02/03/2011 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/02/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/14/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/14/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/14/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 01/14/2011 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 01/14/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/08/2011 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/07/2011 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/23/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 12/22/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/20/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/15/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 12/14/2010 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 12/09/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 12/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 12/01/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 11/11/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/08/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 11/02/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 10/29/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/29/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 10/28/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/27/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 10/25/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/21/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 10/20/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/20/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 10/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/08/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/02/2010 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 09/28/2010 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/24/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/24/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 09/20/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/09/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/09/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 09/07/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 09/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 09/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/01/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 09/01/2010 |
| EDWARDS LIFESCIENCES | <u>IMR ETLOGIX₂ MITRAL</u> | 09/01/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/01/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/20/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/20/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/19/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/10/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 08/05/2010 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/28/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/24/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/22/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/14/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/06/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/02/2010 |
| EDWARDS LIFESCIENCES | <u>GEOFORM</u> <u>ANNULOPLASTY</u> | 06/26/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/26/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/26/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/25/2010 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 06/04/2010 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/02/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 05/19/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> ANN | 05/16/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> ANN | 05/16/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/16/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 05/14/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 05/07/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 05/01/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> P | 04/30/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 04/29/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> C | 04/25/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 04/25/2010 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/25/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/22/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/18/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/14/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/09/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/08/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/08/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/02/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/01/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 03/31/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 03/30/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 03/30/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/26/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 03/26/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/25/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 03/24/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 03/24/2010 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 03/24/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/19/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/11/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 02/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 02/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 02/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 02/23/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/19/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 02/17/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/16/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/10/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/10/2010 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 02/04/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 02/04/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 01/26/2010 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/14/2010 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 01/07/2010 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 01/07/2010 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 12/28/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/24/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/21/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/18/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 12/14/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/10/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/10/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 12/10/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/10/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/09/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/07/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/03/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/03/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/01/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/30/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/30/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/30/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 11/25/2009 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 11/25/2009 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/18/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/18/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/14/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 11/14/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/05/2009 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 10/30/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/30/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/29/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/29/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/29/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 10/28/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 10/28/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/28/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/28/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/23/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/19/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/14/2009 |
| EDWARDS | <u>COSGROVE-EDWARDS</u> | 10/13/2009 |

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| LIFESCIENCES | <u>ANN</u> | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 10/13/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/08/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/05/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/01/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 10/01/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/30/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 09/25/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 09/08/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 09/08/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 09/08/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 09/08/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 09/02/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 09/01/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/28/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/26/2009 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 08/25/2009 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/22/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/21/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/19/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/15/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/08/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/06/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/04/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/04/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/03/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 07/30/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/30/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/29/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 07/24/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/22/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/17/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/11/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/11/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/11/2009 |
| EDWARDS | <u>COSGROVE-EDWARDS</u> | 07/08/2009 |

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| LIFESCIENCES | <u>ANN</u> | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 07/08/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 07/06/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/03/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/29/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/26/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/24/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/18/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 06/18/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/18/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/18/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/18/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/17/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/16/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 06/16/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/12/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/12/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/09/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/09/2009 |
| ST. JUDE MEDICAL, PU | <u>TAILOR ANNULOPLASTY</u> | 06/05/2009 |

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| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/29/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 05/29/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/28/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/28/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 05/26/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/26/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-</u> <u>MCCARTHY-</u> | 05/26/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/13/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/07/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/06/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 05/06/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 05/01/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/21/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/21/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/16/2009 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 04/16/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 04/15/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/14/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 04/09/2009 |

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| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/06/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/04/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/03/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 04/03/2009 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 04/02/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/02/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 04/02/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 03/24/2009 |
| ST. JUDE MEDICAL BRA | <u>TAILOR ANNULOPLASTY</u> | 03/20/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/13/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/11/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/11/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/03/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 03/02/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/25/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 02/16/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 02/16/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/11/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/11/2009 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 02/10/2009 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCINECES | <u>COSGROVE-EDWARDS ANN</u> | 02/09/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 02/03/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 01/27/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/27/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/26/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 01/15/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/09/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 01/05/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 01/05/2009 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 01/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 01/05/2009 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 01/05/2009 |
| EDWARD LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/31/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/24/2008 |
| EDWARDS LIFECIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/24/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/24/2008 |
| EDWARDS | <u>EDWARDS MC3 TRICUSPI</u> | 12/22/2008 |

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| LIFESCIENCES | | |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/22/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 12/22/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 12/22/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/19/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/19/2008 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 12/17/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 12/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 12/08/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/02/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/02/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 12/02/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 12/02/2008 |
| EDWARDS LIFESCINECES | <u>EDWARDS MC3 TRICUSPI</u> | 12/01/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/20/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 11/12/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 11/12/2008 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 11/12/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 11/06/2008 |
| EDWARD LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 11/04/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 11/04/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 11/04/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/29/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 10/29/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 10/29/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/29/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 10/29/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/29/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/28/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 10/23/2008 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/23/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/21/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/20/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/20/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 10/17/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/16/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/16/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 10/14/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 10/14/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/14/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/14/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/14/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 10/08/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/07/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 10/07/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 09/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 09/29/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 09/24/2008 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 09/23/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 09/23/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 09/23/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 09/23/2008 |
| EDWARDS LIFESCIENCES | <u>MCCARTHY MYXO</u> <u>ETLOGI</u> | 09/19/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 09/17/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 09/17/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 09/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 09/12/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 08/27/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 08/27/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/26/2008 |
| EDWARDS LIFESCIENCE | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 08/25/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/25/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/21/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/21/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 08/21/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/19/2008 |
| EDWARDS | <u>GEOFORM</u> | 08/13/2008 |

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| LIFESCIENCES | <u>ANNULOPLASTY</u> | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/13/2008 |
| EDWARDS LIFESCIENCES | <u>GEOFORM ANNULOPLASTY</u> | 08/13/2008 |
| EDWRDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/13/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/12/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/11/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/11/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/07/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/07/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/06/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/05/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 08/05/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 08/04/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 08/04/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/04/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 08/01/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 08/01/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/31/2008 |
| EDWARDS | <u>CARPENTIER-</u> | 07/31/2008 |

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| LIFESCIENCES | <u>MCCARTHY-</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/31/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 07/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 07/28/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/25/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/24/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/24/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/24/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 07/24/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/24/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 07/22/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/22/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/22/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/22/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 07/22/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 07/21/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/17/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/17/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/16/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 07/16/2008 |

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| LIFESCIENCES | <u>P</u> | |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 07/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>C</u> | 07/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/14/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/14/2008 |
| EDWARDS LIFESCIENCES | <u>GEOFORM</u> <u>ANNULOPLASTY</u> | 07/14/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/11/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/07/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 07/07/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS</u> <u>ANN</u> | 07/03/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/01/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 07/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 07/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-</u> <u>MCCARTHY-</u> | 07/01/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-</u> <u>MCCARTHY-</u> | 06/30/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/30/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS</u> <u>P</u> | 06/30/2008 |
| EDWARDS | <u>CARPENTIER-EDWARDS</u> | 06/30/2008 |

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| LIFESCIENCES | <u>C</u> | |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/30/2008 |
| EDWARDS LIFESCIENCES | <u>COSGROVE-EDWARDS ANN</u> | 06/30/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/27/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 06/25/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/25/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/25/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/19/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS C</u> | 06/19/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER- MCCARTHY-</u> | 06/19/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/19/2008 |
| EDWARDS LIFESCIENCES | <u>EDWARDS MC3 TRICUSPI</u> | 06/06/2008 |
| EDWARDS LIFESCIENCES | <u>CARPENTIER-EDWARDS P</u> | 06/04/2008 |



Department of Veterans Affairs

PROFICIENCY REPORT

SECTION A - INDIVIDUAL REPORTED ON

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|---------------------------------------|--------------------------------|-------------------------------------|---|--|
| 1. NAME (Last-first-middle) (b)(6) | | 2. SOCIAL SECURITY NUMBER (b)(6) | 3. NAME AND LOCATION OF FACILITY VA HEALTH CARE SYSTEM CHICAGO IL | 4. FACILITY NO. 978A |
| 5. GRADE/STEP CHIEF 04 | 6. POSITION TITLE PHYSICIAN | | 7. PROB. REV. DUE | 8. PERIOD COVERED BY REPORT FROM 06-07-01 TO 06-07-01 |
| 9. SERVICE MEDICAL SERVICE | | 10. DATE OF BIRTH (b)(6) | 11. NO. OF YRS. IN VA MED. SVC. 1 YEARS | |
| 12. DUTY BEING PERFORMED | | | | |

SECTION B - REPORT OF PROFICIENCY

| INSTRUCTIONS TO RATER | LEGEND |
|--|---|
| <p>Carefully read Instructions in Part 6 before completing form. Rate one or more of the categories (items 13 through 16) as appropriate to duties and responsibilities of the individual and in all instances Personal Qualities (Category V). Narrative summary to support overall evaluation is required in Section D. Refer to Supplement to MP-5, Part II, Chapter 6, concerning procedures for low satisfactory and unsatisfactory ratings.</p> | <p>Unsatisfactory - Has not met reasonable expectations. Low Satisfactory - Usually met reasonable expectations but performance sometimes marginal. Satisfactory - Fully met and sometimes exceeded expectations. High Satisfactory - Usually exceeded reasonable expectations by a substantial margin. Outstanding - Consistently exceeded reasonable expectations to an exceptional degree.</p> |
| <p>13. CATEGORY I - CLINICAL COMPETENCE (Includes examination, diagnosis, therapeutic-ability, effectiveness in emergencies, patient management, consultations, specialty skills and record keeping)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>14. CATEGORY II - EDUCATIONAL COMPETENCE (Includes effectiveness in teaching, monitoring and coordinating educational activities (planning, evaluating and documenting))</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>15. CATEGORY III - RESEARCH AND DEVELOPMENT (Includes ability to identify and define significant Research and Development problems, to plan and execute a precise research program and to generate effective reports and results worthy of publication. Communicates and promotes the broad use of the results of Research and Development)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>16. CATEGORY IV - ADMINISTRATIVE COMPETENCE (Includes supervisory ability, effectiveness in planning, program planning, administrative judgment, decision willingness and correspondence and reporting)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>17. CATEGORY V - PERSONAL QUALITIES (Includes emotional stability, dependability, relations with staff and community, eliciting cooperation, handling groups and adherence to ethical standards)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |

SECTION C - OVERALL EVALUATION

| | | | | | |
|--------------------|---|---|---------------------------------------|--|---|
| 18. OVERALL RATING | <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |
|--------------------|---|---|---------------------------------------|--|---|

SECTION D - NARRATIVE SUMMARY BY RATING OFFICIAL

19. COMMENTS (Comments are required for each rated category and particularly on those elements in which the individual shows exceptional strengths or weaknesses or a change from previous rating. Briefly describe the employee's potential for advancement to higher clinical or executive positions. If in a supervisory capacity, comment on employee's concern for the VA mission and responsiveness to public and agency policies, including such areas as equal employment opportunity, employment of disabled veterans and other handicapped individuals).

Dr. (b)(6) has done an outstanding job as chief of the echocardiography lab, outpatient clinic attending and CCU/consult attending. She has demonstrated excellent leadership in the echo lab and outstanding clinical acumen in her other roles. She is committed to providing outstanding care to veterans and high level teaching to house staff and students.

Dr. (b)(6)'s clinical privileges have been reviewed in light of existing quality assurance data and are current. Her mental and physical health appears to be satisfactory to carry out her assigned duties.

NOTE - REVERSE CARBONS BEFORE COMPLETING THIS SIDE

19. COMMENTS (Continued)

20. CONTINUING EDUCATION ACTIVITIES ARE
 SATISFACTORY UNSATISFACTORY

21. ENTRIES ON THIS FORM ARE BASED ON
 A. FREQUENT OR DAILY CONTACT
 B. INFREQUENT OR OCCASIONAL CONTACT
 C. FREQUENT OBSERVATION OF WORK RESULTS
 D. INFREQUENT OBSERVATION OF WORK RESULTS

22. NO. OF MONTHS UNDER MY SUPERVISION

23A. DATE: (b)(6)
23B. POSITION: (b)(6)
23C. DATE: 3/25/02

SECTION E - COMMENTS OF APPROVING OFFICIAL

(If in disagreement with rating, refer to DM&S Supplement to MP-S, Part II, Chapter 6, App. 6A, General Instructions)

24. COMMENTS
(b)(6)
25B. POSITION: CHIEF CL
25C. DATE: 3/27/02

SECTION F - RATED EMPLOYEE

26. I HAVE SEEN THE APPROVED RATING AND HAVE HAD THE OPPORTUNITY TO DISCUSS IT
 YES NO

27. I AM INTERESTED IN ADVANCEMENT TO A HIGHER CLINICAL OR ADMINISTRATIVE POSITION
 YES NO

NOTE - Comments concerning your rating may be submitted in writing to your supervisor and will be filed in your Official Personnel Folder and/or Board Action Folder.
PROFESSIONAL CAREER DEVELOPMENT PROGRAM - Physicians and Dentists who are interested in assignment to centralized positions, and incumbents of centralized positions and staff Dentists interested in reassignment.
I have been provided with VA Form 10-5349 (Check if applicable)

28A. SIGNATURE: (b)(6)
28B. DATE: 7/1/02



SECTION A - INDIVIDUAL REPORTED ON

| | | | | | | | |
|---------------------------------------|--|-------------------------------------|--|--|--|--|--|
| 1. NAME (Last-first-middle) (b)(6) | | 2. SOCIAL SECURITY NUMBER (b)(6) | | 3. NAME AND LOCATION OF FACILITY VA HEALTH CARE SYSTEM CHICAGO | | 4. FACILITY NO. 578A | |
| 5. GRADE/STEP CHIEF | | 6. POSITION TITLE PHYSICIAN | | 7. PROB. REV. DUE | | 8. PERIOD COVERED BY REPORT FROM: 06-07-02 TO: 06-07-03 | |
| 9. SERVICE MEDICAL SERVICE | | | | 10. DATE OF BIRTH (b)(6) | | 11. NO. OF YRS. IN VA MED. SVC. 2 YEARS | |
| 12. DUTY BEING PERFORMED | | | | | | | |

SECTION B - REPORT OF PROFICIENCY

| INSTRUCTIONS TO RATER | LEGEND |
|--|---|
| <p>Carefully read Instructions in Part 6 before completing form. Rate one or more of the categories (items 13 through 16) as appropriate to duties and responsibilities of the individual and in all instances Personal Qualities (Category V). Narrative summary to support overall evaluation is required in Section D. Refer to Supplement to MP-5, Part II, Chapter 6, concerning procedures for low satisfactory and unsatisfactory ratings.</p> | <p>Unsatisfactory - Has not met reasonable expectations. Low Satisfactory - Usually met reasonable expectations but performance sometimes marginal. Satisfactory - Fully met and sometimes exceeded expectations. High Satisfactory - Usually exceeded reasonable expectations by a substantial margin. Outstanding - Consistently exceeded reasonable expectations to an exceptional degree.</p> |
| <p>13. CATEGORY I - CLINICAL COMPETENCE (Includes examination, diagnosis, therapeutic-ability, effectiveness in emergencies, patient management, consultations, specialty skills and record keeping)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>14. CATEGORY II - EDUCATIONAL COMPETENCE (Includes effectiveness in teaching, monitoring and coordinating educational activities (planning, evaluating and documenting))</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>15. CATEGORY III - RESEARCH AND DEVELOPMENT (Includes ability to identify and define significant Research and Development problems, to plan and execute a precise research program and to generate effective reports and results worthy of publication. Communicates and promotes the broad use of the results of Research and Development)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>16. CATEGORY IV - ADMINISTRATIVE COMPETENCE (Includes supervisory ability, effectiveness in planning, program planning, administrative judgment, decision willingness and correspondence and reporting)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input checked="" type="checkbox"/> Outstanding</p> | |
| <p>17. CATEGORY V - PERSONAL QUALITIES (Includes emotional stability, dependability, relations with staff and community, eliciting cooperation, handling groups and adherence to ethical standards)</p> <p><input type="checkbox"/> UNSATISFACTORY <input type="checkbox"/> LOW SATISFACTORY <input type="checkbox"/> SATISFACTORY <input type="checkbox"/> HIGH SATISFACTORY <input type="checkbox"/> Outstanding</p> | |

SECTION C - OVERALL EVALUATION

18. OVERALL RATING

UNSATISFACTORY LOW SATISFACTORY SATISFACTORY HIGH SATISFACTORY Outstanding

SECTION D - NARRATIVE SUMMARY BY RATING OFFICIAL

19. COMMENTS (Comments are required for each rated category and particularly on those elements in which the individual shows exceptional strengths or weaknesses or a change from previous rating. Briefly describe the employee's potential for advancement to higher clinical or executive positions. If in a supervisory capacity, comment on employee's concern for the VA mission and responsiveness to public and agency policies, including such areas as equal employment opportunity, employment of disabled veterans and other handicapped individuals).

Dr. (b)(6) continues to provide outstanding leadership in her role as director of the echocardiography laboratory and as a clinical cardiologist. She is highly knowledgeable, conscientious and compassionate towards veterans' needs.

Dr. (b)(6)'s clinical privileges have been reviewed in light of existing quality assurance data and are current. Her mental and physical health appears to be satisfactory to carry out her assigned duties.

NOTE - REVERSE CARBONS BEFORE COMPLETING THIS SIDE

19. COMMENTS (Continued)

20. CONTINUING EDUCATION ACTIVITIES ARE

SATISFACTORY UNSATISFACTORY

21. ENTRIES ON THIS FORM ARE BASED ON

A. FREQUENT OR DAILY CONTACT C. FREQUENT OBSERVATION OF WORK RESULTS
 B. INFREQUENT CONTACT D. INFREQUENT OBSERVATION OF WORK RESULTS

22. NO. OF MONTHS UNDER MY SUPERVISION

23A. (b)(6)

23B. POSITION
Chief of Cardiology

23C. DATE
3/18/03

SECTION E - COMMENTS OF APPROVING OFFICIAL

(If in disagreement with rating, refer to DM&S Supplement to MP-5, Part II, Chapter 6, App. 6A, General Instructions)

24. COMMENTS

25A. (b)(6)

25B. POSITION
Chief of Cardiology

25C. DATE
8/1/03

SECTION F - RATED EMPLOYEE

26. I HAVE SEEN THE APPRAISAL AND DISCUSS IT
 YES NO

26. I HAVE SEEN THE APPRAISAL AND DISCUSS IT
(b)(6)

27. I Am Interested In Advancement To A Higher Clinical Or Administrative Position
 YES NO

NOTE - Comments Folder and/or Board Action Folder. PROFESSIONAL CAREER DEVELOPMENT PROGRAM - Physicians and Dentists who are interested in assignment to centralized positions, and incumbents of centralized positions and staff Dentists interested in reassignment. I have been provided with VA Form 10-5349 (Check if applicable)

28A. SIGNATURE OF EMPLOYEE

(b)(6)

28B. DATE
6/24/03

PROFICIENCY REPORT

SECTION A - INDIVIDUAL REPORTED ON

| | | | | | | | |
|---|--|-------------------------------------|--|--|--|--|--|
| 1. NAME (Last, first, middle) (b)(6) | | 2. SOCIAL SECURITY NUMBER (b)(6) | | 3. NAME AND LOCATION OF FACILITY VA HEALTH CARE SYSTEM CHICAGO | | 4. FACILITY NO. 578A | |
| 5. GRADE/STEP CHIEF 05 | | 6. POSITION TITLE PHYSICIAN | | 7. PROB. REV. DUE | | 8. PERIOD COVERED BY REPORT FROM 06-07-04 TO 06-07-05 | |
| 9. SERVICE MEDICAL SERVICE | | | | 10. DATE OF BIRTH (b)(6) | | 11. NO. OF YRS. IN VA MED. SVC. 4 YEARS | |
| 12. DUTY BEING PERFORMED | | | | | | | |

SECTION B - REPORT OF PROFICIENCY

INSTRUCTIONS TO RATER

Carefully read Instructions in Part 6 before completing form. Rate one or more of the categories (items 13 through 16) as appropriate to duties and responsibilities of the individual and in all instances Personal Qualities (Category V). Narrative summary to support overall evaluation is required in Section D. Refer to Supplement to MP-5, Part II, Chapter 6, concerning procedures for low satisfactory and unsatisfactory ratings.

LEGEND

Unsatisfactory - Has not met reasonable expectations.
 Low Satisfactory - Usually met reasonable expectations but performance sometimes marginal.
 Satisfactory - Fully met and sometimes exceeded expectations.
 High Satisfactory - Usually exceeded reasonable expectations by a substantial margin.
 Outstanding - Consistently exceeded reasonable expectations to an exceptional degree.

| | | | | |
|---|---|---------------------------------------|--|---|
| 13. CATEGORY I - CLINICAL COMPETENCE (Includes examination, diagnosis, therapeutic ability, effectiveness in emergencies, patient management, consultations, specialty skills and record keeping) | | | | |
| <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |
| 14. CATEGORY II - EDUCATIONAL COMPETENCE (Includes effectiveness in teaching, monitoring and coordinating educational activities (planning, evaluating and documenting)) | | | | |
| <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |
| 15. CATEGORY III - RESEARCH AND DEVELOPMENT (Includes ability to identify and define significant Research and Development problems, to plan and execute a precise research program and to generate effective reports and results worthy of publication. Communicates and promotes the broad use of the results of Research and Development) | | | | |
| <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |
| 16. CATEGORY IV - ADMINISTRATIVE COMPETENCE (Includes supervisory ability, effectiveness in planning, program planning, administrative judgment, decision willingness and correspondence and reporting) | | | | |
| <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |
| 17. CATEGORY V - PERSONAL QUALITIES (Includes emotional stability, dependability, relations with staff and community, eliciting cooperation, handling groups and adherence to ethical standards) | | | | |
| <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |

SECTION C - OVERALL EVALUATION

| | | | | |
|---|---|---------------------------------------|--|---|
| 18. OVERALL RATING | | | | |
| <input type="checkbox"/> UNSATISFACTORY | <input type="checkbox"/> LOW SATISFACTORY | <input type="checkbox"/> SATISFACTORY | <input type="checkbox"/> HIGH SATISFACTORY | <input checked="" type="checkbox"/> Outstanding |

SECTION D - NARRATIVE SUMMARY BY RATING OFFICIAL

19. COMMENTS (Comments are required for each rated category and particularly on those elements in which the individual shows exceptional strengths or weaknesses or a change from previous rating. Briefly describe the employee's potential for advancement to higher clinical or executive positions. If in a supervisory capacity, comment on employee's concern for the VA mission and responsiveness to public and agency policies, including such areas as equal employment opportunity, employment of disabled veterans and other handicapped individuals).

(b)(6)

Dr. (b)(6) continues to do a superb job and to provide outstanding leadership as director of The Lakeside CBOC's echocardiography laboratory. In addition she provides a high level of teaching to staff and a high level of compassionate patient care to veterans.

Dr. (b)(6)'s clinical privileges have been reviewed in the light of available quality assurance data, and they are both current and appropriate. She attended the annual training in Safety, Infection Control, Radiation Safety, The Elderly, and MSDS.

NOTE - REVERSE CARBONS BEFORE COMPLETING THIS SIDE

19. COMMENTS (Continued)

20. CONTINUING EDUCATION ACTIVITIES ARE

SATISFACTORY

UNSATISFACTORY

21. ENTRIES ON THIS FORM ARE BASED ON

A. FREQUENT OR DAILY CONTACT

C. FREQUENT OBSERVATION OF WORK RESULTS

D. INFREQUENT OBSERVATION OF WORK RESULTS

22. NO. OF MONTHS UNDER MY SUPERVISION

(b)(6)

23B. POSITION

Chief of Med. Lab. & BOC

23C. DATE

2/2/85

SECTION E - COMMENTS OF APPROVING OFFICIAL

(If in disagreement with rating, refer to DM&S Supplement to MP-5, Part II, Chapter 6, App. 6A, General Instructions)

24. COMMENTS

25A. SIGNATURE

(b)(6)

25B. POSITION

Chief of Med. Lab. & BOC

25C. DATE

8-22-85

SECTION F - RATED EMPLOYEE

26. I HAVE SEEN THE APPROVED RATING AND HAVE HAD THE OPPORTUNITY TO DISCUSS IT

YES NO

(b)(6)

27. I Am Interested In Advancement To A Higher Clinical Or Administrative Position

YES NO

NOTE - Comment submitted in writing to your supervisor and will be filed in your Official Personnel Folder and/or Board Action Folder.

PROFESSIONAL CAREER DEVELOPMENT PROGRAM - Physicians and Dentists who are interested in assignment to centralized positions, and incumbents of centralized positions and staff Dentists interested in reassignment.

I have been provided with VA Form 10-5349 (Check if applicable)

28A. SIGNATURE OF EMPLOYEE

(b)(6)

28B. DATE



NOV 26 2008

(b)(6)

President and CEO
Northwestern Memorial Healthcare
251 East Huron Street
Chicago, IL 60611

Dear Mr. (b)(6)

(b)(4)

links to related information are also included at this site. If you have any questions, do not hesitate to contact (b)(6) at (240) 276-(b)(6)

Sincerely yours,

(b)(6)

(b)(6) MSN, RN
Chief, Special Investigations Branch
Division of Bioresearch Monitoring
Office of Compliance
Center for Devices and
Radiological Health

REC'D
DEC 3 2008
REGULATORY AFFAIRS



Edwards Lifesciences

EDWARDS LIFESCIENCES
ONE EDWARDS WAY
IRVINE, CA 92614

Click on one to indicate FMEA type:
 DESIGN
 PROCESS
 SYSTEM

FMEA Number: 6989

Revision: C

| | | |
|----------------------------|--|---------|
| Description: | Process FMEA for Annuloplasty Ring, Model 5100 | |
| Business Unit: | HVT | |
| DHF Number: | 6994 | |
| Revision Date: | 11/2/2006 | |
| Suppliers/Plants Affected: | Irvine | |
| Prepared By: | (b)(6) | 11/2/06 |

Team/Approval Signatures:

| | | | |
|----------------------|-------------|--------------------------------------|----------|
| R&D: | Sign here: | (b)(6) | 11/2/06 |
| | Print Name: | (b)(6) R&D Engineer | Date: |
| Clinical Programs: | Sign here: | (b)(6) | 11/3/06 |
| | Print Name: | (b)(6) g, Sr. Dir. Clinical Programs | Date: |
| Manufacturing: | Sign here: | (b)(6) | 11/02/06 |
| | Print Name: | (b)(6) Manufacturing Engineer | Date: |
| Quality Engineering: | Sign here: | (b)(6) | 11/2/06 |
| | Print Name: | (b)(6) Quality Engineer | Date: |
| Regulatory Affairs: | Sign here: | (b)(6) | 11/3/06 |
| | Print Name: | (b)(6) Sr. Regulatory Associate | Date: |
| Marketing: | Sign here: | (b)(6) | 11.2-06 |
| | Print Name: | (b)(6) Product Manager | Date: |

Ratings:

| | | | |
|---------------------------------------|-----|---|-----------|
| Severity of Failure Effect | S | = | 1 to 4 |
| Probability of Occurrence | O | = | 1 to 5 |
| Detection with Current Design Control | D | = | 1 to 5 |
| Risk Priority Number | RPN | = | S x O x D |

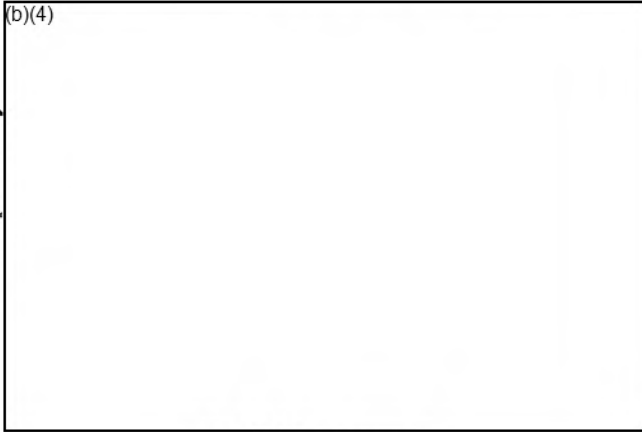
Severity Levels:

| | | |
|----------|---|---|
| Critical | = | 4 |
| Major A | = | 3 |
| Major B | = | 2 |
| Minor | = | 1 |

Acronyms:

RI = Receiving Inspection
DQ/DV = Design Qualification/Verification

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IT MUST NOT BE REPRODUCED OR DISCLOSED TO OTHERS WITHOUT PRIOR WRITTEN APPROVAL.

| | | |
|---|---------|---|
| FMEA #: 6989 | Rev.: C | Description: Process FMEA for Annuloplasty Ring, Model 5100 |
| Introduction: | (b)(4) | |
| Risk Summary: | | |
| Residual Risk: | | |
| <p style="text-align: center;">Distribution of RPN Scores for FMEA #6989</p> <div style="text-align: center;">  <p style="margin-left: 100px;">Frequency</p> <p style="margin-right: 100px;">RPN Scores</p> </div> <p style="text-align: center;">Figure 1 – Distribution of RPN Scores for FMEA #6989</p> | | |

FMEA Matrix Instructions**Edwards Lifesciences**

| COL. # | COLUMN HEADER | COLUMN DETAILS |
|--------|---|----------------|
| 1 | Component / Function | (b)(4) |
| 2 | Potential Failure Mode | |
| 3 | Potential Effects of Failure | |
| 4 | Sev | |
| 5 | Potential Cause(s) / Mechanism's of Failure | |
| 6 | Occ | |
| 7 | Current Design Controls | |
| 8 | Det | |
| 9 | RPN | |
| 10 | Recommended Action(s) | |
| 11 | P R I | |
| 12 | Responsible Person & Target Date | |
| 13 | Actions Taken | |
| 14 | Sev | |
| 15 | Occ | |
| 16 | Det | |
| 17 | RPN | |

Revision Change HistoryEdwards Lifesciences

| FMEA #: 6989 | | Description: Process FMEA for Annuloplasty Ring, Model 5100 | |
|--------------|-----------|---|----------------------|
| Revision | Rev. Date | Change | Reason/Justification |
| A | 1/23/2006 | (b)(4) | |
| B | 5/3/2006 | | |
| | | | |
| | | | |
| | | | |
| | | | |
| C | 11/2/2006 | | |
| | | | |
| | | | |
| | | | |

Revision Change History

Edwards Lifesciences

| | | |
|--|--|--------|
| | | (b)(4) |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Click on one to Indicate type of FMEA: <input type="checkbox"/> DESIGN <input checked="" type="checkbox"/> PROCESS <input type="checkbox"/> SYSTEM | | | | | | | | | | DESCRIPTION: Process FMEA for Annuloplasty Ring, Model 5100 | | | | | | | | |
|--|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|---|-------|----------------------------------|---------------|----------------|-------|-------|-------|--------|
| 0 | 1 | Existing Conditions | | | | | | | | Corrective Actions | | | | Action Results | | | | |
| | | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | |
| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
| 1 | Machining the ring. | | | | | | | | | | | | | | | | | |
| 2 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 3 | (b)(4) | | | | | | | | | | | | | | | | | |
| 4 | (b)(4) | | | | | | | | | | | | | | | | | |
| 5 | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 6 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 7 | (b)(4) | | | | | | | | | | | | | | | | | |
| 8 | Passivate and Rinse Rings | | | | | | | | | | | | | | | | | |
| 9 | (b)(4) | | | | | | | | | | | | | | | | | |
| 10 | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | |
|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--|--------|
| 11 | | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 12 | Cleaning ring | | | | | | | | | | | | | | | | | | |
| 13 | (b)(4) | | | | | | | | | | | | | | | | | | |
| 14 | (b)(4) | | | | | | | | | | | | | | | | | | |
| 15 | Issue Implantable Materials | | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 16 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 17 | (b)(4) | | | | | | | | | | | | | | | | | |
| 18 | (b)(4) | | | | | | | | | | | | | | | | | |
| 19 | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | |
|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--------|--|
| 20 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) | |
| 21 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 22 | Prepare Form 4149 | | | | | | | | | | | | | | | | | | |
| 23 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 24 | Prepare ID tag | | | | | | | | | | | | | | | | | | |

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Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--------|
| 25 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 26 | Apply Silicone band to Ring using suture wrap. | | | | | | | | | | | | | | | | | |
| 27 | (b)(4) | | | | | | | | | | | | | | | | | |
| 28 | (b)(4) | | | | | | | | | | | | | | | | | |
| 29 | (b)(4) | | | | | | | | | | | | | | | | | |
| 30 | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

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|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--------|
| 31 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 32 | (b)(4) | | | | | | | | | | | | | | | | | |
| 33 | (b)(4) | | | | | | | | | | | | | | | | | |
| 34 | Issue Cloth | | | | | | | | | | | | | | | | | |
| 35 | (b)(4) | | | | | | | | | | | | | | | | | |
| 36 | (b)(4) | | | | | | | | | | | | | | | | | |
| 37 | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | | | |
|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--------|--------|--|--------|
| 38 | | | | (b)(4) | | | | | | | | | | | | | | (b)(4) | | | |
| 39 | | | | (b)(4) | | | | | | | | | | | | | | | (b)(4) | | |
| 40 | Cut and Iron Cloth and Trim | | | | | | | | | | | | | | | | | | (b)(4) | | |
| 41 | (b)(4) | | | | | | | | | | | | | | | | | | | | (b)(4) |
| 42 | (b)(4) | | | | | | | | | | | | | | | | | | | | (b)(4) |
| 43 | (b)(4) | | | | | | | | | | | | | | | | | | | | (b)(4) |
| 44 | (b)(4) | | | | | | | | | | | | | | | | | | | | (b)(4) |

FMEA # 6989 , Rev. C

Edwards Lifesciences

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|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--|--------|
| 45 | | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 46 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 47 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 48 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 49 | Sew Cloth Butt Joint | | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | |
|----------|--|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--|--|
| 50 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 51 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 52 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 53 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 54 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 55 | Sew In-and-Out Stitch Through Silicone | | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | |
|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--|--|
| 56 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 57 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 58 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 59 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 60 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 61 | | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--|--------|--|
| 62 | | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) | |
| 63 | | (b)(4) | | | | | | | | | | | | | | | | | | |
| 64 | | (b)(4) | | | | | | | | | | | | | | | | | | |
| 65 | Sew Seam around ring | | | | | | | | | | | | | | | | | | | |
| 66 | | (b)(4) | | | | | | | | | | | | | | | | | | |
| 67 | | (b)(4) | | | | | | | | | | | | | | | | | | |
| 68 | | (b)(4) | | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | | |
|----------|---|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--|--------|
| 69 | | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 70 | | | (b)(4) | | | | | | | | | | | | | | | | |
| 71 | Sew Green Suture Mark, Commissure Marks, and Center Mark | | | | | | | | | | | | | | | | | | |
| 72 | | (b)(4) | | | | | | | | | | | | | | | | | |
| 73 | | (b)(4) | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 74 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 75 | | (b)(4) | | | | | | | | | | | | | | | | |
| 76 | | (b)(4) | | | | | | | | | | | | | | | | |
| 77 | | (b)(4) | | | | | | | | | | | | | | | | |
| 78 | | (b)(4) | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 79 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 80 | Attach ID Tag | | | | | | | | | | | | | | | | | |
| 81 | | (b)(4) | | | | | | | | | | | | | | | | |
| 82 | | | | | | | | | | | | | | | | | | |
| 83 | | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 84 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 85 | | | | | | | | | | | | | | | | | | |
| 86 | Boiling process | | | | | | | | | | | | | | | | | |
| 87 | | (b)(4) | | | | | | | | | | | | | | | | |
| 88 | | | | | | | | | | | | | | | | | | |
| 89 | | | | | | | | | | | | | | | | | | |
| 90 | | | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/Function/Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N |
|----------|------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|
| 91 | (b)(4) | | | | | | | | | | | | | | | | |
| 92 | (b)(4) | | | | | | | | | | | | | | | | |
| 93 | Holder molding | | | | | | | | | | | | | | | | |
| 94 | (b)(4) | | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/Function/Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|------------------------------|------------------------|-------------------------------------|-------------|---|-------------|------------------------------------|-------------|-------------|-----------------------|-------------|----------------------------------|---------------|-------------|-------------|-------------|-------------|--------|
| 95 | | | (b)(4) | | | | | | | | | | | | | | | |
| 96 | | | (b)(4) | | | | | | | | | | | | | | | |
| 97 | | | (b)(4) | | | | | | | | | | | | | | | |
| 98 | (b)(4) | | (b)(4) | | | | | | | | | | | | | | | (b)(4) |
| 99 | (b)(4) | | (b)(4) | | | | | | | | | | | | | | | |
| 100 | | | (b)(4) | | | | | | | | | | | | | | | |

FMEA # 6989 , Rev. C

Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 101 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 102 | (b)(4) | | | | | | | | | | | | | | | | | |
| 103 | Ultrasonic Cleaning | | | | | | | | | | | | | | | | | |
| 104 | (b)(4) | | | | | | | | | | | | | | | | | |
| 105 | Pad Printing | | | | | | | | | | | | | | | | | |
| 106 | (b)(4) | | | | | | | | | | | | | | | | | |
| 107 | (b)(4) | | | | | | | | | | | | | | | | | |

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Edwards Lifesciences

| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------------|------------------------|--|-------------|---|-------------|---------------------------------------|-------------|-------------|--------------------------|-------------|--|---------------|-------------|-------------|-------------|-------------|--------|
| 108 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 109 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 110 | Assemble ring to holder | | | | | | | | | | | | | | | | | |
| 111 | | (b)(4) | | | | | | | | | | | | | | | | |
| 112 | | (b)(4) | | | | | | | | | | | | | | | | |
| 113 | | (b)(4) | | | | | | | | | | | | | | | | |

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| Line No. | Component/Function/Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|------------------------------|------------------------|-------------------------------------|-------------|---|-------------|------------------------------------|-------------|-------------|-----------------------|-------------|----------------------------------|---------------|-------------|-------------|-------------|-------------|--------|
| 114 | | (b)(4) | | | | | | | | | | | | | | | | (b)(4) |
| 115 | | (b)(4) | | | | | | | | | | | | | | | | |
| 116 | | (b)(4) | | | | | | | | | | | | | | | | |
| 117 | | (b)(4) | | | | | | | | | | | | | | | | |
| 118 | | (b)(4) | | | | | | | | | | | | | | | | |
| 119 | | (b)(4) | | | | | | | | | | | | | | | | |

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| Line No. | Component/ Function/ Operation | Potential Failure Mode | Potential Effect(s) of Failure Mode | S e v | Potential Cause(s) / Mechanism(s) of Failure Mode | O c c | Design / Process / System Controls | D e t | R P N | Recommended Action(s) | P R I | Responsible Person & Target Date | Actions Taken | S e v | O c c | D e t | R P N | |
|----------|--------------------------------|------------------------|-------------------------------------|-------|---|-------|------------------------------------|-------|-------|-----------------------|-------|----------------------------------|---------------|-------|-------|-------|-------|--------|
| 120 | (b)(4) | | | | | | | | | | | | | | | | | |
| 121 | (b)(4) | | | | | | | | | | | | | | | | | (b)(4) |
| 122 | (b)(4) | | | | | | | | | | | | | | | | | |

Report Number: 8371

Report Title Title: Packaging Validation, Myxo ETlogix Annulopasty Rings

| | | | |
|---------------------|------------------------|-----------------------|---------------------|
| Report Number: 8371 | Protocol Revision: N/A | Date Issued: 11/14/06 | Number of Pages: 18 |
|---------------------|------------------------|-----------------------|---------------------|

Report Title: Packaging, Validation, Myxo ETlogix Annulopasty Rings

Prepared By: (b)(6) Packaging Engineer

Technical Summary Approvals:

| DIVISION | SIGNATURE | DATE |
|-----------------------|--|----------|
| Packaging Engineering | (b)(6) Packaging Engineer | 11/16/06 |
| R&D Engineering | (b)(6) EW Staff Engineer | 11/16/06 |
| Quality Engineering | (b)(6) Quality Engineer | 11/16/06 |
| MFG. Engineering | (b)(6) EW Senior Engineer | 11/16/06 |
| Regulatory Affairs | (b)(6) Regulatory Affairs Associate | 11/16/06 |
| Marketing | (b)(6) Product Manager | 11-16-06 |

1 PURPOSE

1.1 (b)(4)

1.2

1.3

1.4

2 SCOPE

2.1 (b)(4)

Table 1: Packaging Components

| Description | Material | Part Number |
|----------------------------------|----------|---------------------|
| Inner Tray, 3.56"x3.04"x1.48" | (b)(4) | 195917001 |
| Outer Tray, 4.75"x4.34"x1.53" | | 195916001 |
| Inner Lid, 3.58"x3.18" | | 141664001 |
| Blank Outer Lid, 4.36x4.78" | | 141663002 (only) |
| Folding Carton | | 195920001 |

2.2

(b)(4)

Table 2: Myxo ETlogix Part Numbers

| Ring Size | Part Number |
|-----------|-------------|
| 26mm | 693401026 |
| 28mm | 693401028 |
| 30mm | 693401030 |
| 32mm | 693401032 |
| 34mm | 693401034 |
| 36mm | 693401036 |
| 38mm | 693401038 |
| 40mm | 693401040 |

2.3

(b)(4)

2.4

(b)(4)

2.5

2.6

2.7

2.8 (b)(4)

2.9

2.9.1 (b)(4)

2.10 (b)(4)

2.10.1 (b)(4)

2.10.2 (b)(4)

(b)(4)

3 DEVIATIONS

3.1 (b)(4)

3.2

3.3 (b)(4)

3.4

3.5

3.6

3.7 (b)(4)

3.8

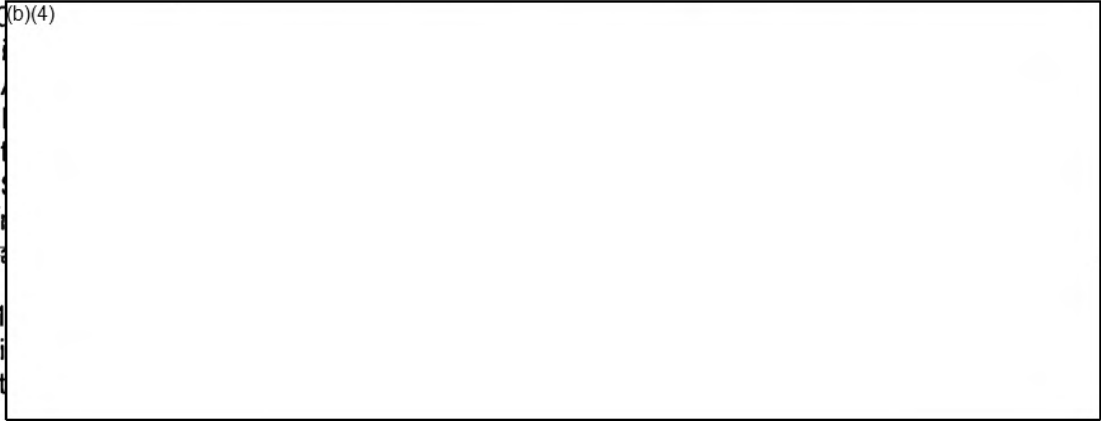
3.9

Report Number: 8371

Report Title Title: Packaging Validation, Myxo ETlogix Annulopasty Rings

3.10 (b)(4)

3.11



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4 MATERIALS USED

4.1 See **Table 3** for a listing of the materials and lot numbers used for testing.

Table 3: Material Used

| Description | Part Number | Quantity | Testing Done on Part by Edwards | Lot Number |
|----------------------------------|---|----------|------------------------------------|---|
| Carton | 195920001 | 121 | (b)(4) | 58040536 |
| Shipper | Edwards Warehousing Standard RSC 12x12x6 | 12 | | NA |
| Model 5100 Ring Assemblies | 693401040 (See Section 5.1.1) | 120 | | See Attached Shop orders in Attachment 1 |
| Inner Tray | 195917001 | 336 | | 58181401-1 |
| Outer Tray | 195916001 | 453 | | 58156934-1 |
| Outer Tyvek (Blank) | 141663002 | 240 | | N2022f3020 |
| Inner Tyvek | 141664001 | 240 | | N2022f3002 |
| Outer Tyvek (Preprinted) | 195901001 | 120 | | 581520170-1 |

5 TESTING PERFORMED

5.1 Sterile Barrier and Product Damage Testing

5.1.1 (b)(4)

5.1.1.1 (b)(4)

5.1.2 (b)(4)

5.1.3

5.1.4

5.2 Mold Verification Testing

5.2.1 (b)(4)

Table 4: First Articles

| Part Number | First Article # |
|-------------|-----------------|
| 195916001 | 8924 |
| 195917001 | 3070 |
| 195920001 | 8925 |

5.2.2 (b)(4)

5.2.3

(b)(4)

5.2.4 Inner Tray Molding Process Performance Testing

5.2.4.

(b)(4)

5.2.4.1.1

(b)(4)

5.2.4.2

(b)(4)

5.2.4.2.1

(b)(4)

5.2.5 Outer Tray Molding Process Performance Testing

5.2.5.1

(b)(4)

5.2.5.1.1

(b)(4)

5.2.5.1

(b)(4)

(b)(4)

5.2.6 Sealing Process Qualification

5.2.6.1 Outer Trays

5.2.6.1.1

(b)(4)

5.2.6.1.1.1

(b)(4)

5.2.6.1.2

(b)(4)

5.2.6.1.2.1

(b)(4)

5.2.6.2 Inner Trays

5.2.6.2.1

(b)(4)

5.2.6.2.1.1

(b)(4)

6 TEST RESULTS

6.1 Sterile Barrier Testing

6.1.1

(b)(4)

(b)(4)

6.1.1.1 (b)(4)

6.2 Product Damage Testing

6.2.1 (b)(4)

6.2.1.1 (b)(4)

6.2.1.2 (b)(4)

6.2.1.3 (b)(4)

6.3 First Article

6.3.1 (b)(4)

6.4 Process Capability

6.4.1 Inner Trays

6.4.1.1 (b)(4)

6.4.1.1.1 (b)(4)

6.4.2 Outer Trays

6.4.2.1 (b)(4)

6.4.2.1.1 (b)(4)

6.5 Sealing Process Parameter Verification

6.5.1 (b)(4)

Table 4: Burst Test Data (all units is in H₂O)

| | Belco #1 | | Belco #2 | |
|---|--------------------|-----------------------|--------------------|-----------------------|
| | Low Setting LTL | High Setting (LTL) | Low Setting LTL | High Setting (LTL) |
| | (b)(4) | | | |
| Inner Tray with Tyvek | (b)(4) | | | |
| Outer Tray with Blank Tyvek | | | | |
| Outer Tray with Preprinted Tyvek | | | | |

6.5.2 Outer Trays with Blank Tyvek Lidstock

6.5.2.1 (b)(4)

6.5.2.2

6.5.3 Outer Trays with Preprinted Tyvek Lidstock

6.5.3.1 (b)(4)

6.5.3.1.1 (b)(4)

6.5.3.2 (b)(4)

6.5.3.3

6.5.4 Inner Trays

6.5.4.1 (b)(4)

6.5.4.2

7 SUMMARY AND ANALYSIS

7.1 Sterile Barrier Testing

7.1.1 (b)(4)

7.2 Product Damage Testing

7.2.1 (b)(4)

7.2.1.1 (b)(4)

7.2.1.2 (b)(4)

[Redacted content]

(b)(4)

[Redacted content]

7.2.1.3 (b)(4)

[Redacted content]

7.2.2

(b)(4)

[Redacted content]

(b)(4)

7.3 First Article

7.3.1

7.3.2

7.3.3

(b)(4)

7.4 Process Capability Study

7.4.1

7.4.2

(b)(4)

7.5 Sealing Process Parameter Verification

7.5.1

7.5.2

7.5.3

(b)(4)

8 MBC

8.1

(b)(4)

9 CONCLUSION

9.1 (b)(4)

9.2

9.3

9.4

9.4.1 (b)(4)

9.4.2

9.5 (b)(4)

10 REFERENCES

10.1 (b)(4)

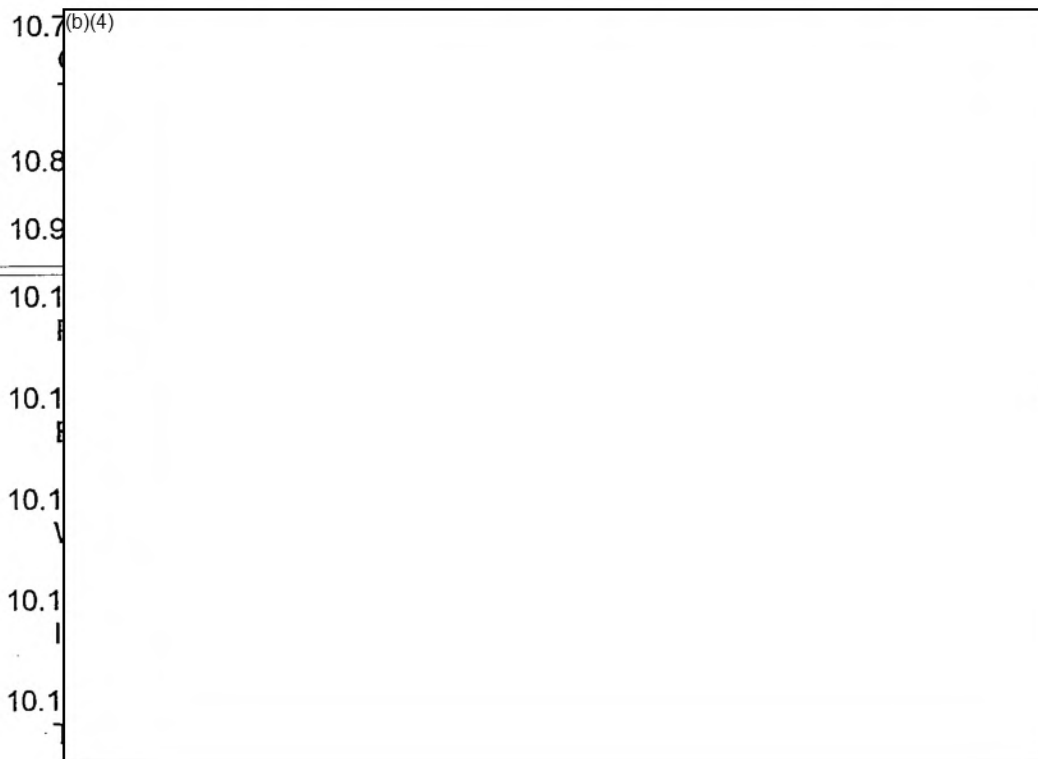
10.2

10.3

10.4

10.5

10.6



Interim Report Number: 9098

Protocol Title: Packaging PQ, Model 5100, Myxo ETlogix

Protocol *of Euk 11/16/06*

| | | | |
|---------------------|-------------|-----------------------|--------------------|
| Report Number: 9098 | Revision: A | Date Issued: 11/16/06 | Number of Pages: 9 |
|---------------------|-------------|-----------------------|--------------------|

| |
|--|
| Interim Report Title: |
| Packaging PQ, Model 5100, Myxo ETlogix |

| |
|--|
| Prepared By: (b)(4) Packaging Engineer |
|--|

Validation Protocol Approvals:

| DIVISION | SIGNATURE | DATE |
|-----------------------|--|----------|
| Packaging Engineering | (b)(6) Packaging Engineer | 11/16/06 |
| R&D Engineering | (b)(6) EW Staff Engineer | 11/16/06 |
| Quality Engineering | (b)(6) Quality Engineer | 11/16/06 |
| MFG. Engineering | (b)(6) EW Senior Engineer | 11/16/06 |
| Regulatory Affairs | (b)(6) Regulatory Affairs Associate | 11/16/06 |
| Marketing | (b)(6) Product Manager | 11-16-06 |

1 PURPOSE

1.1 (b)(4)

2 SCOPE

2.1 (b)(4)

2.2

Table 1: Machines and Tools Qualified per this Interim Report

| | |
|-------------------------|--------------------------------------|
| Sealer | Belco Number 2 (Serial Number 8055) |
| Inner Tray Nesting Tool | Part Number 394551 |
| Outer Tray Nesting Tool | Part Number 300169 (Belco PN 170424) |

2.3 (b)(4)

Table 2: Packaging Components

| Description | Material | Part Number |
|----------------------------------|----------|------------------|
| Inner Tray, 3.56"x3.04"x1.48" | (b)(4) | 195917001 |
| Outer Tray, 4.75"x4.34"x1.53" | | 195916001 |
| Inner Lid, 3.58"x3.18" | | 141664001 |
| | | |
| Outer Lid, 4.36x4.78" | | 141663002(blank) |

2.4 (b)(4)

2.5

| | |
|-----|--------|
| 2.4 | (b)(4) |
| 2.5 | |

Table 3: Myxo ETlogix Part Numbers

| Ring Size | Part Number |
|-----------|-------------|
| 26mm | 693401026 |
| 28mm | 693401028 |
| 30mm | 693401030 |
| 32mm | 693401032 |
| 34mm | 693401034 |
| 36mm | 693401036 |
| 38mm | 693401038 |
| 40mm | 693401040 |

2.6 (b)(4)

| | |
|-----|--------|
| 2.6 | (b)(4) |
|-----|--------|

2.7 (b)(4)

2.7.1 (b)(4)

Table 4: Burst Specification

| Tray PN | Tyvek PN | Min Burst Specification |
|-----------|------------------------|-------------------------|
| 195917001 | 141664001 | (b)(4) |
| 195916001 | 141663002 or 195901001 | |

2.8 (b)(4)

Table 5: Sealing Parameters per SOP2827

| Parameter | Belco #1 | Belco #2 |
|-------------|----------|----------|
| Pressure | (b)(4) | |
| Temperature | | |
| Time | | |

3 EQUIPMENT AND SAMPLES

3.1 (b)(4)

3.1.1 (b)(4)

3.2 (b)(4)
 3.3
 3.4

3.4.1 (b)(4)
 3.4.2

3.4.2.1 Burst Tester Used

3.4.2.1.1 (b)(4)
 3.4.2.1.2

3.4.3 (b)(4)

3.5 Samples to be used

3.5.1 (b)(4)

Table 6: Validation Samples

| Part Number | Quantity | Description | Lot Numbers |
|-------------|----------|-------------------------|-------------|
| 195917001 | 215 | Inner Tray | 5818401-1 |
| 195916001 | 200 | Outer Tray | 581856934-1 |
| 141664001 | 215 | Inner Tyvek Lid | 58132098 |
| 141663002 | 200 | Outer Tyvek Lid (Blank) | 58179039-4 |

4 DEVIATIONS

4.1 (b)(4)

5 TESTING PERFORMED AND RESULTS

| | |
|-----|--------|
| 5.1 | (b)(4) |
| 5.2 | |
| 5.3 | |

Table 7: Operators

| Production Runs | Operators |
|----------------------------|-----------|
| 5:45am-8:00am (11/10/06) | (b)(4) |
| 11:30am-12:55pm (11/13/06) | |
| 1:10pm-2:15pm (11/9/06) | |

| | |
|-----|--------|
| 5.4 | (b)(4) |
| 5.5 | |
| 5.6 | |

Table 9: LTL of Each Run and the Combined Runs

| Run | | Quantity | Average (in H ₂ O) | Standard Deviation | LTL (in H ₂ O) |
|-------------|-------|----------|-------------------------------|--------------------|---------------------------|
| 5:45-8 | Inner | (b)(4) | | | |
| | Outer | | | | |
| 11:30-12:55 | Inner | | | | |
| | Outer | | | | |
| 1:10-2:15 | Inner | | | | |
| | Outer | | | | |
| Combined | Inner | | | | |
| | Outer | | | | |

5.7 (b)(4)

5.7.1 (b)(4)

5.7.1.1 (b)(4)

5.7.1.2

5.7.1.3

5.7.2 (b)(4)

5.7.2.1 (b)(4)

5.7.2.2 (b)(4)

5.7.2.3

6 CONCLUSION

6.1 (b)(4)

6.2

6.3

6.4 (b)(4)

6.5

7 References

7.1 (b)(4)

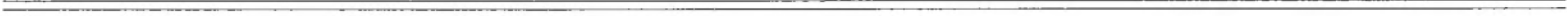
7.2

7.3 (b)(4)
7.4
7.5
7.6
7.7
7.8
7.9

7.10 (b)(4)
7.11
7.12
7.13

8 RECORDS

8.1 (b)(4)



DESIGN VERIFICATION OF ANNULOPLASTY RING, MODEL 5100

Addendum Report A

Protocol No. 7430

Prepared By: (b)(6) _____ Date: 5/5/06
(b)(6) HVT Quality Engineering

Approved By: (b)(6) _____ Date: 5/8/06
(b)(6) ~~HVT R&D~~ Engineering

Approved By: (b)(6) _____ Date: 5/5/06
(b)(6) HVT Quality Engineering

Approved By: (b)(6) _____ Date: 05/08/06
(b)(6) Manufacturing Engineering

Approved By: (b)(6) _____ Date: 5/8/06
(b)(6) Regulatory Affairs

Approved By: (b)(6) _____ Date: 5-5-06
(b)(6) Marketing

1 PURPOSE

1.1

(b)(4)

2 SCOPE

2.1

2.2

2.3

(b)(4)

3 TEST ARTICLES AND CONTROLS

3.1

(b)(4)

(b)(4)

3.2

4 EQUIPMENT

(b)(4)

4.1 (b)(4)

4.2

4.3

4.4

5 PROCEDURE, SPECIMEN CONDITIONING

5.1 (b)(4)

5.2

5.2.1 (b)(4)

5.2.2

Test Cycle Parameters

Temperature: (b)(4)

Time:

Dry Time:

(b)(4)

5.2.3

6 RESULTS

6.1 (b)(4)

(b)(4)

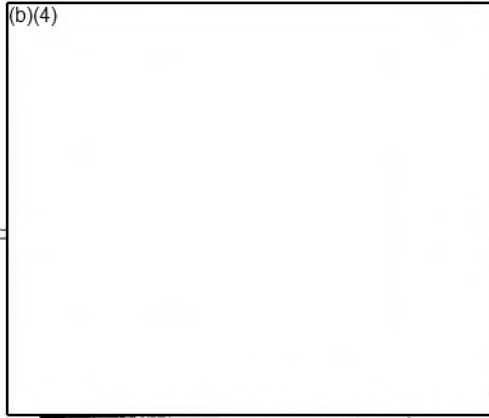


Figure 1: Applied Load Direction

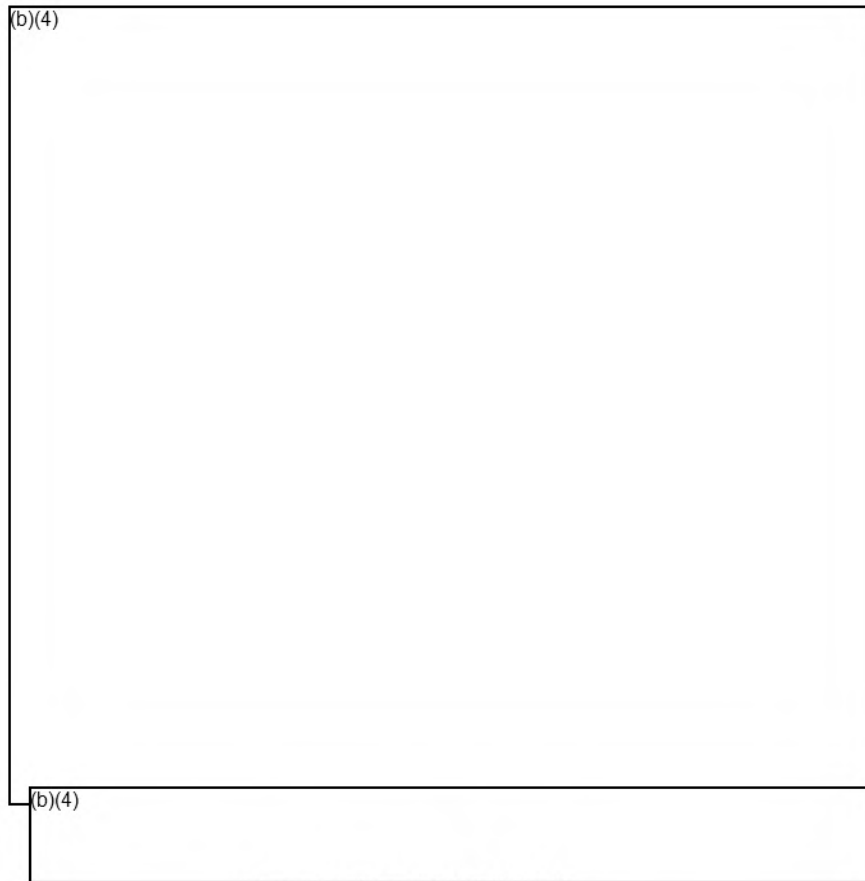


Figure 2: Tensile Test Setup

The following table, Table 1, summarizes the yield strength of the test articles.

Table 1: Ring Yield Strength Data

| Ring # | Offset Yield Strength (lb) | Offset Yield Strength (gm) |
|----------------|----------------------------|----------------------------|
| 6200 | (b)(4) | (b)(4) |
| 6201 | (b)(4) | (b)(4) |
| 6202 | (b)(4) | (b)(4) |
| 6203 | (b)(4) | (b)(4) |
| 6204 | (b)(4) | (b)(4) |
| 6205 | (b)(4) | (b)(4) |
| 6206 | (b)(4) | (b)(4) |
| 6207 | (b)(4) | (b)(4) |
| 6208 | (b)(4) | (b)(4) |
| 6209 | (b)(4) | (b)(4) |
| 6210 | (b)(4) | (b)(4) |
| 6211 | (b)(4) | (b)(4) |
| 6212 | (b)(4) | (b)(4) |
| Mean | (b)(4) | (b)(4) |
| Std Dev | (b)(4) | (b)(4) |

6.2 (b)(4)

(b)(4)

7 DEVIATIONS

7.1 (b)(4)

7.2

7.3

8 CONCLUSION

8.1 (b)(4)

9 REFERENCE DOCUMENTS/ STANDARDS

9.1 (b)(4)

9.2

9.3

9.4

(b)(4)

9.5

9.6

Table 2. Standard References

(b)(4)

10 MICROBIOLOGY/BIOLOGY/CHEMISTRY QUALIFICATION

10.1

(b)(4)

ATTACHMENT #1
StatGraphics Sample Size Determination

Sample-Size Determination

(b)(4)

The StatAdvisor

(b)(4)

ATTACHMENT #2
Test Article Shop Orders

*** EDWARDS MATERIAL REQUIREMENTS LIST ***

PAGE: 1

PART NO: 195813840 RQSTR: ILA REV: B U/M: EA QTY: 19 S/O NO: EG6D0622

RING, MACHINED, MODEL 5100 TOXICITY/STERILITY: D METHOD NO: 01 ISSUE DATE: 04/19/2006 DUE DATE: 04/28/2006

(b)(4)

**** END OF PICK LIST ****

CHARGE MATERIALS & Labor
TO CC # EO ~~6321~~ 01

Quetta
4/20/06

575

SF010A-B

EDWARDS SHOP ORDER

D

PAGE: 2



EG6D0622



P/N 195813840 RQSTR: ILA REV: B U/M: EA



000019

RING, MACHINED, MODEL 5100 TOXICITY/STERILITY: D METHOD NO: 01 ISSUE DATE: 04/19/2006 DUE DATE: 04/28/2006
 REL ID: ECN42688 GS: N REL CODE: F UP DATE: 00 LATEX - PROD: PKG: HT: N
 LC: Y SC: N PLNR: EGP B/C: 13 QTY SPLIT OFF: SPLIT AT OPER: APPROVAL: DATE: PL: 2440 S/L: N

(b)(4)

(b)(4)

1/1/06

01



Edwards

CRITICAL DIMENSION INSPECTION DATA SHEET

Part Number: 195813-840

Rev: A Router / S/O #: P/O. 4406RC

Inspector: (b)(4)

Date: 4-17-06
19 Jan 4-14-06

| Box Dim. # | (b)(4) | Actual Dim |
|---------------|--------|------------|
| Specification | (b)(4) | |
| Max/Min | (b)(4) | |
| Tool / ID# | (b)(4) | |
| Sample # | (b)(4) | |
| 1 | (b)(4) | |
| 2 | (b)(4) | |
| 3 | (b)(4) | |
| 4 | (b)(4) | |
| 5 | (b)(4) | |
| 6 | (b)(4) | |
| 7 | (b)(4) | |
| 8 | (b)(4) | |
| 9 | (b)(4) | |
| 10 | (b)(4) | |
| 11 | (b)(4) | |
| 12 | (b)(4) | |
| 13 | (b)(4) | |
| 14 | (b)(4) | |
| 15 | (b)(4) | |
| 16 | (b)(4) | |
| 17 | (b)(4) | |
| 18 | (b)(4) | |
| 19 | (b)(4) | |
| 20 | (b)(4) | |



**BENDICK
PRECISION
INC.**

Edwards Lifesciences
Cardiovascular Group
1212 Alton Parkway
Irvine, Ca. 92606

CERTIFICATION OF CONFORMANCE

QUANTITY

DESCRIPTION

51

195813-840 Rev B
Ring-Myxomatous

- 1.
- 2.
- 3.
- 4.
- 5.

(b)(4)

(b)(4)

Signed: _____ (b)(6) _____

Date: 4/06/07

Per Our Invoice #: 13194

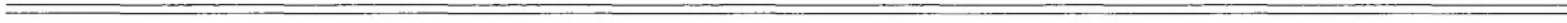
*** EDWARDS MATERIAL REQUIREMENTS LIST ***

PART NO: 195813840 RQSTR: ILA REV: B U/M: EA QTY: 0 S/O NO: EG6D062278

(b)(4)

TOTAL LINE ITEMS WITH PICK CODE "P" 0

**** END OF PICK LIST ****



Enterprise Change Request (ECR) Number: ECR54962

Initiator: (b)(6)
Vault: (ChgHistory)

Submission Date: 07/19/2006 13:01:19:065
Life Cycle State: Closed

Sign-Off History

DETAILED INFORMATION

Summary of Change

(b)(4)

Change Category
Expedite Priority
Highest Release Level
Send to Collaboration
Site/Business Center Intiated

CRB Representatives
Configuration Specialist
Manufacturing
Marketing
Quality Assurance
Regulatory Affairs
Research/Development
Designated Approver

(b)(4)

Regulatory Actions Required? False

510(K) JTF
510(K) Approval
IDE Supplement
IDE Annual Report
PMA Supplement
PMA Annual Report Required

(b)(4)

HAS CHANGE ITEM(s)

Change Item Number
ID Number
Classification
Change Type
Release Code
Disposition Required
Is this a Purchased Part?
Last Update Date
Vault

(b)(4)

Enterprise Change Request (ECR) Number: ECR54962

Initiator: (b)(6)
Vault: (ChgHistory)

Submission Date: 07/19/2006 13:01:19:065
Life Cycle State: Closed

Sign-Off History

DETAILED INFORMATION

Summary of Change

(b)(4)

- Change Category
- Expedite Priority
- Highest Release Level
- Send to Collaboration
- Site/Business Center Initiated

- CRB Representatives
- Configuration Specialist
- Manufacturing
- Marketing
- Quality Assurance
- Regulatory Affairs
- Research/Development
- Designated Approver

(b)(4)

Regulatory Actions Required? False

- 510(K) JTF
- 510(K) Approval
- IDE Supplement
- IDE Annual Report
- PMA Supplement
- PMA Annual Report Required

(b)(4)

HAS CHANGE ITEM(s)

- Change Item Number
- ID Number
- Classification
- Change Type
- Release Code
- Disposition Required
- Is this a Purchased Part?
- Last Update Date
- Vault

(b)(4)



To: Model 5100 Regulatory
Documentation

Date: November 8, 2006

cc: DHF # 6994

From: (b)(4)
EW Staff Engineer

(b)(4)

Subject: Justification for Statements Added to Myxo ETlogix Annuloplasty Ring DFU

Purpose

(b)(4)

Scope

(b)(4)

Discussion

(b)(4)

(b)(4)



Consideration of the Posterior Leaflet

(b)(4)

Visualization of the Myxo ring AP distance

(b)(4)

Table 1: Comparison of Sizer Length to Myxo ETlogix Annuloplasty Ring AP Dimension

| Size | Sizer Length (mm) | Myxo ETlogix AP Dimension (mm)* |
|------|-------------------|---------------------------------|
| 26mm | (b)(4) | |
| 28mm | | |
| 30mm | | |
| 32mm | | |
| 34mm | | |
| 36mm | | |
| 38mm | | |
| 40mm | | |

*NOTE: AP Dimension of ring taken at outer diameter of cloth.

(b)(4)

Conclusions

(b)(4)



To: Model 5100 Regulatory Documentation

Date: November 8, 2006

cc: DHF # 6994

From: (b)(4)
EW Staff Engineer

(b)(4)

11/8/06

Subject: Implantation Characteristics Justification for the Myxo ETlogix (Model 5100) Annuloplasty Ring with Holder

Purpose

(b)(4)

Scope

(b)(4)

Background

(b)(4)

Discussion

(b)(4)



Table 1: Implant Characteristics and Techniques:

| Implant Characteristic / Technique | Related Accessories | Justification for Use with Model 5100 Ring |
|------------------------------------|---------------------|--|
| (b)(4) | | |
| (b)(4) | | |
| (b)(4) | | |



(b)(4)

(b)(4)

Table 2. Accessories used for the Model 5100 Ring:

| Accessory | Accessory Model Number | Justification for Use with Model 5100 Ring |
|-----------|------------------------|--|
| (b)(4) | | |

Conclusions

(b)(4)



Attachment A: Sizing and Sizing Method

(b)(4)

Changes in Model 5100 Ring Design Compared to Physio and Classic

(b)(4)

Analysis of Sizing Methods

(b)(4)

(b)(4)



(b)(4)



Table 3. Dimensional Comparison between the Model 5100 and Physio rings.

| Ring Size (mm) | Model 5100 Ring | | | Physio Ring Model 4450 | | |
|----------------|---------------------|--|---|------------------------|--|---|
| | A (mm) ³ | Anterior- Posterior Distance (mm) ³ | Commissure- Commissure Distance ² (mm) | A (mm) ^{1,3} | Anterior- Posterior Distance (mm) ³ | Commissure- Commissure Distance ² (mm) |
| 26 | (b)(4) | | | | | |
| 28 | | | | | | |
| 30 | | | | | | |
| 32 | | | | | | |
| 34 | | | | | | |
| 36 | | | | | | |
| 38 | | | | | | |
| 40 | | | | | | |

(b)(4)

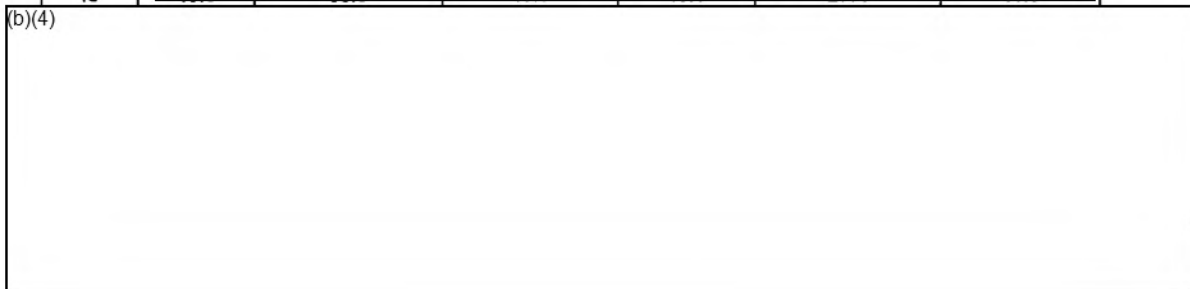




Figure 1. Dimensions of Model 5100 Ring and Physio Ring Model 4450. **NOTE:** Figure depicts the ring core only. Dimensions are measured to the core of the ring, without cloth or silicone.

MODEL 5100 RING

PHYSIO RING

(b)(4)





To: Model 5100 Regulatory
Documentation

Date: November 8, 2006

cc: DHF # 6994

From: (b)(4) (b)(4)
EW Staff Engineer

11/8/06

**Subject: Design Validation of the Myxo ETlogix (Model 5100) Annuloplasty Ring—
Update Based on Feedback from Multiple Implanting Surgeons**

Purpose

(b)(4)

Scope

(b)(4)

Background

(b)(4)



Figure 1. Dimensional Comparison between the Model 5100 and Physio rings.

| Ring Size (mm) | Model 5100 Ring | | | Physio Ring Model 4450 | | |
|----------------|---------------------|--|--|------------------------|--|--|
| | A (mm) ¹ | Anterior- Posterior Distance (mm) ² | Commissure-Commissure Distance ² (mm) | A (mm) ^{1,3} | Anterior- Posterior Distance (mm) ¹ | Commissure-Commissure Distance ² (mm) |
| 26 | (b)(4) | | | | | |
| 28 | | | | | | |
| 30 | | | | | | |
| 32 | | | | | | |
| 34 | | | | | | |
| 36 | | | | | | |
| 38 | | | | | | |
| 40 | | | | | | |

(b)(4)

Figure 2. Dimensions of Model 5100 Ring and Physio Ring Model 4450. **NOTE:** Figure depicts the ring core only. Dimensions are measured from the inner edge of the core of the ring, without cloth or silicone.

MODEL 5100 RING

PHYSIO RING

(b)(4)



Discussion

(b)(4)

Figure 3: Design Characteristics of Model 5100 Ring

| Characteristic | Predicate |
|----------------|-----------|
| (b)(4) | |

(b)(4)

(b)(4)



Figure 4: Implanting Surgeons

| Surgeon | # Implants | # Surveys or direct feedback |
|---------|------------|------------------------------|
| (b)(4) | | |

(b)(4)

Conclusions

(b)(4)

References

1. (b)(4)
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.

Comparison of Annuloplasty Model Holders

| Feature | Physio/IMR | Cosgrove | Mc3 | GeoForm | Mxyo ETlogix |
|---------|------------|----------|-----|---------|--------------|
|---------|------------|----------|-----|---------|--------------|

| | | | | | |
|--------|--|--|--|--|--|
| (b)(4) | | | | | |
|--------|--|--|--|--|--|

| | | | | | |
|--------|--|--|--|--|--|
| (b)(4) | | | | | |
|--------|--|--|--|--|--|



Edwards Lifesciences, LLC

Regulatory Meeting with FDA
October 14, 2008

Agenda



- Introductions
- Purpose of regulatory meeting
- Response to Edward's letter dated August 15, 2008
- Primary Difference Between the Physio and Myxo ETlogix Rings
- Primary Difference Between the GeoForm and Myxo ETlogix Rings
- Comments

Introductions



■ FDA

- CDRH/OC
- CDRH/ODE
- CDRH/OCD
- OE
- LOS-DO

■ Edwards Lifesciences, Llc

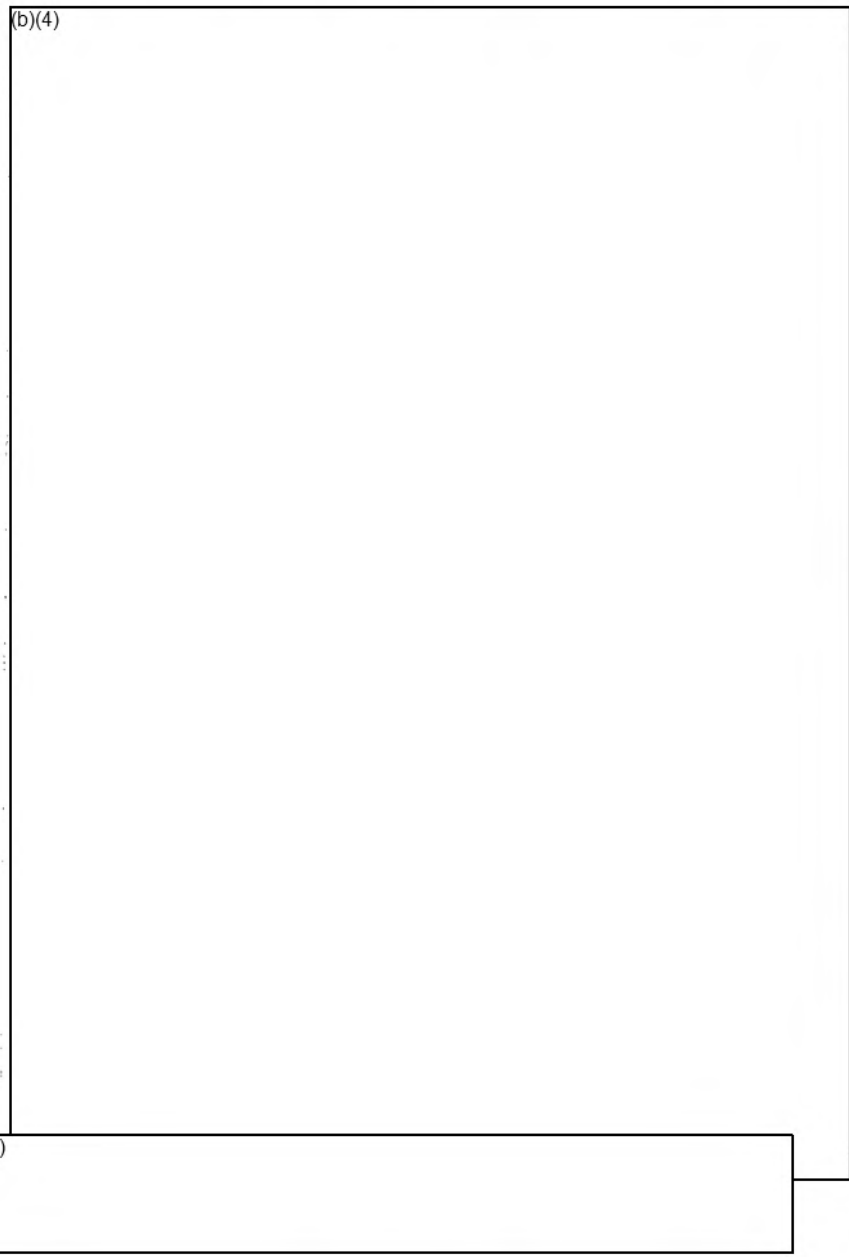
- (b)(6) Chief Regulatory Officer
- (b)(6), VP Regulatory Affairs
- (b)(6), VP Product Safety
- (b)(6), Corporate VP, HVT
- (b)(6)

Response to Edward's letter dated August 15, 2008



- (b)(4)
-

FLOWCHART B - IS IT A TECHNOLOGY OR PERFORMANCE CHANGE?

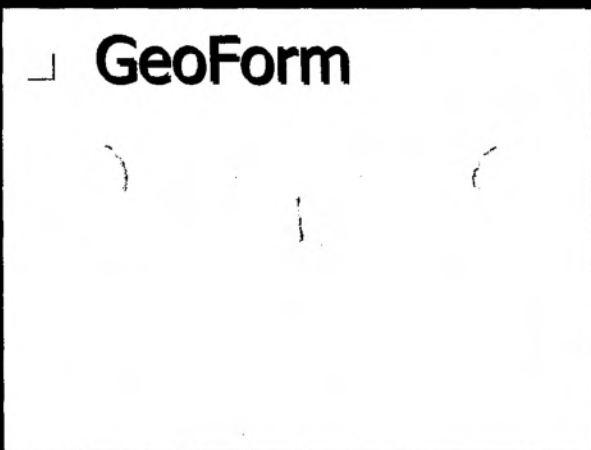


From Main Chart

Primary Difference Between the Physio and Myxo ETlogix Rings

- (b)(4)
-
-
-
-

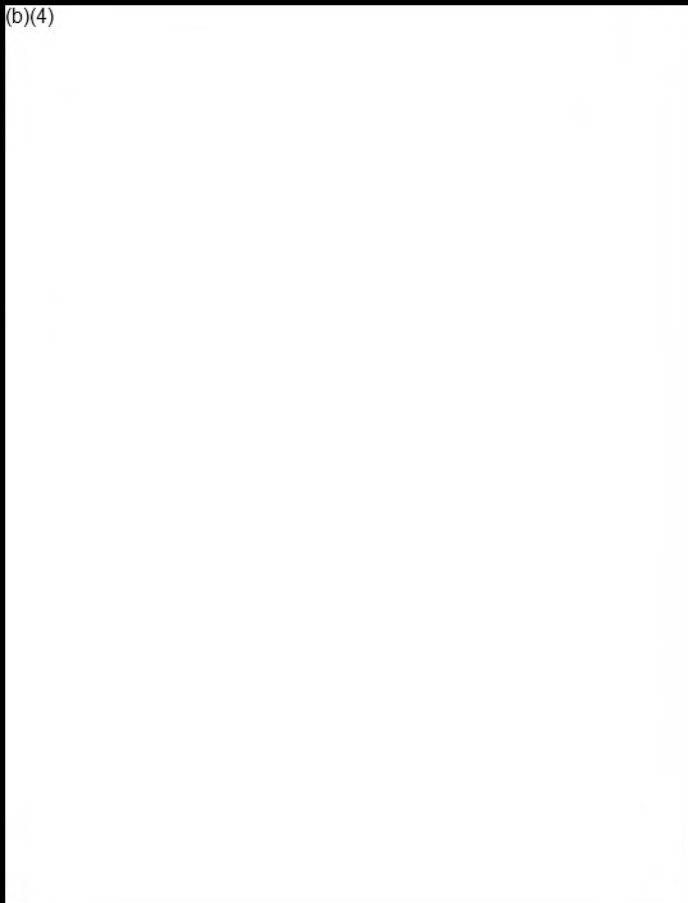
Primary Difference Between the GeoForm and Myxo ETlogix Rings



- Myxo ETlogix



-
-
-



Comments





To: Model 5100 File

Date: November 11, 2005

cc:

From:

(b)(4); (b)(6)

Project Manager

(b)(4); (b)(6)

11/11/05

(b)(4); (b)(6)

Staff

(b)(4); (b)(6)

11/11/05

(b)(4); (b)(6)

Engineer II

(b)(4); (b)(6)

11/11/05

Subject: Design input for the Model 5100 ring, holder, and Model 1155 Mitral Valve Caliper

Purpose

(b)(4)

Background

(b)(4)

Discussion

Model 5100 Ring: (b)(4)

(b)(4)

(b)(4)



(b)(4)

Mitral Valve Calipers and Sizing: (b)(4)

(b)(4)

Implant Schedule (b)(4)

(b)(4)



Edwards

URGENT NOTICE
PRODUCT RETURN
MYXO ETLOGIX ANNULOPLASTY RING Model 5100, All Sizes, All Lots

December 5, 2008

Attention: Risk Management **cc: Department of Cardiac Surgery**

Re: Myxo ETlogix Annuloplasty Ring, Model #'s 5100M26, 5100M28, 5100M30, 5100M32, 5100M34, 5100M36, 5100M38, and 5100M40, Sizes 26mm - 40mm

Dear Valued Customer,

This request to return all Myxo rings to Edwards has been initiated because the FDA questioned the appropriateness of the product's name and disagreed with the company's conclusion that a 510(k) premarket notification was unnecessary prior to distributing the product. These decisions were not prompted by any product performance issues, but instead reflect the company's commitment to being responsive to the FDA. As a result, Edwards is changing the name of the device and has submitted a 510(k) application to the FDA, which is currently under review.

Should you receive questions about the Myxo ring from patients, please inform them that these decisions were not prompted by product performance issues. If you or any of your patients would like to speak with an Edwards representative, the company would be pleased to make available a member of our medical staff.

All Myxo model sizes (26mm through 40mm) are being collected. The affected product codes are 5100M26, 5100M28, 5100M30, 5100M32, 5100M34, 5100M36, 5100M38, and 5100M40.

Please check your inventory for any affected product and return all unused product from your stock to Edwards. Please call **Edwards Customer Service at 888.570.4012** (6:00 AM PDT to 4:30 PM PDT) to arrange for return of any unused product and obtain information about replacement product.

Please return all unused product to: **Edwards Lifesciences LLC**
 Attn: Returned Goods
 1212 Alton Parkway
 Irvine, CA 92614

After you have verified your inventory, please complete the attached Confirmation Form. Please complete and return this form even if you do not have any affected units at your facility. This will allow us to verify the completion of this initiative.

Please return the Confirmation Form by FAX to: 800.422.9329, Attention: Myxo Return Coordinator.

We sincerely regret the inconvenience caused by this action and greatly appreciate your immediate attention to this matter.

Sincerely,

(b)(4)

(b)(6)

Corporate Vice President, Heart Valve Therapy



Edwards

Myxo ETlogix Annuloplasty Ring Return Response

Customer Name _____

Address _____

Contact Name _____ Contact Tel () _____

MYXO RING

Check if no MYXO inventory

| Product Code | Size | Number of units to be returned |
|--------------|------|--------------------------------|
| 5100M26 | 26mm | |
| 5100M28 | 28mm | |
| 5100M30 | 30mm | |
| 5100M32 | 32mm | |
| 5100M34 | 34mm | |
| 5100M36 | 36mm | |
| 5100M38 | 38mm | |
| 5100M40 | 40mm | |

RGA No. _____

Print Name _____ (person completing this form)

Signature _____ Date _____

Please call 888-570-4012 to request an RGA number and if you have any questions.

Please fill in the number of units being returned and the RGA number and Fax completed form to the Return Coordinator at 800-422-9329

Note: Please enter a zero "0" or indicate "none" if you have no inventory to return.



Edwards

IMR ETlogix Annuloplasty Ring Return Response

In order to facilitate the RGA process, please record Serial Numbers prior to contacting Edwards.

IMR ETLOGIX RING

| Product Code | List Serial Numbers to be returned (or enter "0" or "None" if no stock on hand) |
|---------------------|--|
| 4100M24 | |
| 4100M26 | |
| 4100M28 | |
| 4100M30 | |
| 4100M32 | |
| 4100M34 | |

Customer/Hospital Name _____

RGA No. _____

Print Name _____ (person completing this form)

Signature _____ Date _____

Please call 888-570-4012 to request an RGA number and if you have any questions.

Please fill in the serial number(s) of units being returned and the RGA number and Fax completed form to the Return Coordinator at 800-422-9329.

Note: Please enter a zero "0" or indicate "None" if you have no inventory to return.



Edwards Lifesciences

Justification to File

Notification of Product Modifications made to
The GeoForm Annuloplasty Ring (K032250)

McCarthy Myxo ETlogix Annuloplasty Ring, Model 5100

February 27, 2006

Volume 1 of 1

Copy: RA File



To: RA File

Date: February 27, 2006

cc:

From: (b)(4); (b)(6)

RA Associate III

Subject: Decision for Notification of Product Modification

Purpose

(b)(4)

Trade Name

McCarthy Type II Annuloplasty Ring, Mitral Model 5100

Device Description

(b)(4)

Description of Product Modifications

Please refer to **Table 1** for a comparison of the modifications between rings:



Table 1 – Comparison of the GeoForm and McCarthy Type II Ring.

| | GeoForm | Type II |
|-----------------------------|---------|---------|
| K# | (b)(4) | |
| Cloth Material | | |
| Ring Material | | |
| Sewing Ring/Silicone | | |
| Intended Use | | |
| Flex/Rigid | | |
| Open Closed | | |
| Position | | |
| 3-D | | |

Change to the GeoForm Ring:

(b)(4)

▪ **Product Labeling Changes**

(b)(4)

Safety and Effectiveness of Modified Product

(b)(4)



(b)(4)

Table 1 Autoclave sterilization cycle parameters

| | Wrapped/Unwrapped | Cycle Temp | Cycle Time |
|--|-------------------|------------|------------|
| DFU Wrapped/Standard Cycle Specification | (b)(4) | | |
| DFU Flash Cycle Specification | | | |
| Actual Test Cycles Parameters | | | |

(b)(4)

**Ring Tensile Test:
Method:**

(b)(4)

Results:

(b)(4)



(b)(4)

Conclusion: (b)(4)

(b)(4)

Deviations: (b)(4)

(b)(4)

(b)(4)

Suture Pull Out

(b)(4)



Computational Structure Analysis of the Mitral Ring Model 5100 under distributed compression force:

Method:

(b)(4)

Results:

(b)(4)

Computational Structural Analysis of Mitral Ring Model 5100 under Distributed Tensile Force:

Method:

(b)(4)

Results:

(b)(4)

Table 2 – Results for the Maximum Principal Stress Model 4400 and Model 5100

| Anterior-Posterior Direction | Major Axis Direction |
|-------------------------------------|-----------------------------|
| (b)(4) | |



M/B/C # 0751

(b)(4)

Sterilization: (b)(4)

(b)(4)

Summary:

Testing performed for the Model 5100 demonstrated:

- (b)(4)
-
-

| Component | Classic Tricuspid | Type II Model 5100 |
|------------|-------------------|--------------------|
| Metal Ring | (b)(4) | |
| Cloth | (b)(4) | |
| Tubing | (b)(4) | |
| Packaging | (b)(4) | |

(b)(4)

Pyrogen: (b)(4)

(b)(4)



Summary:

(b)(4)

Biocompatibility:

(b)(4)

(b)(4)

Packaging Shelf Life/Accelerated Aging:

(b)(4)

Manufacturing Process:

(b)(4)



▪ **Conclusions**

(b)(4)

Regulatory Assessment

(b)(4)

Applicable Regulatory Documents

(b)(4)



Written by:

Reviewed by:

(b)(4); (b)(6)
[Redacted]
(b)(4); (b)(6)
[Redacted] 2/27/06
Regulatory Affairs Associate III

(b)(4); (b)(6)
[Redacted]
(b)(4); (b)(6)
[Redacted] 3/3/06
Director, HVT Regulatory

Attachments:

- Design Requirements Document
- Main Flow Chart When to File a 510(k) After a Change to a Legally Marketed Device
- Design Validation of the Model 5100 Annuloplasty Ring (memo)
- Protocol #7430
- RD1177
- RD1199
- Suture Pull Out Justification
- 5 Year Shelf Life – in #7430
- MRI Statement Memo
- Implantation Characteristics JTF for Model 5100 (R&D)
- Risk Assessment
- Design FMEA #6988
- Process FMEA #6989
- Cleaning #1653
- Drying #96000161
- MBC 0751
- Biocompatibility – Memo from Chem
- Chemistry – Memo from Chem
- Sterilization – Memo from Micro
- Pyrogen – Memo from Micro MLT2652
- Shelf Life/Acc Age- Pkg – Memo from Micro
- Technical Summary – Packaging #7477
- DFU
- Drawing
- Demonstration of Model 5100 Ring Drawing Equivalence

Regulatory Checklist for the Model 5100 Annuloplasty Ring
Dated 02/16/06

| Testing Required | Pass/Fail | Document Number | Supporting Documentation | Comments |
|---|-----------|-----------------|--------------------------|----------|
| | | | FEA | |
| Computational Structure Analysis - Tensile | (b)(4) | | | |
| Computational Structure Analysis - Compression | | | | |
| | | | R&D Reports | |
| Tensile Testing | (b)(4) | | | |
| Suture Pull Out/ Suture Retention | | | | |
| Ring Removal Force | | | | |
| Shelf Life for Ring Assembly, Silicone, Suture Threads, and Cloth | | | | |
| Implantation Characteristics | | | | |
| | | | | |
| | | | MRC | |
| Shelf Life Validation | (b)(4) | | | |
| Biocompatibility Testing | | | | |
| Sterilization Validation | | | | |
| Moist Heat Resistance | | | | |
| Pyrogen | | | | |
| Chemistry Acceptability Testing | | | | |
| | | | | |
| | | | FMEA | |
| Design FMEA | (b)(4) | | | |
| | | | | |
| | | | | |

Attachments



Edwards Lifesciences

MyxoLogix Mitral Annuloplasty Ring

Model 5100

(Sizes: 26mm – 36mm)

First Human Use Approval Sheet

DHF# 6994

The signatures below indicate approval for "First Human Use" of the MyxoLogix mitral annuloplasty ring without holder.

Project Team Approvals:

(b)(6); (b)(4)

Technical Team Leader R&D

(b)(6); (b)(4)

3/3/06

(b)(6); (b)(4)

R&D

(b)(6); (b)(4)

3/3/06

(b)(6); (b)(4)

Regulatory Affairs

3/3/06

(b)(6); (b)(4)

Quality

3/3/06

(b)(6); (b)(4)

Manufacturing

3/3/06

(b)(6); (b)(4)

Manufacturing Engineering

03/03/06

(b)(6); (b)(4)

Manufacturing Engineering

3/3/06

(b)(6); (b)(4)

Clinical

3/3/06

(b)(6); (b)(4)

Marketing

3-3-2006

(b)(6); (b)(4)

Project Management

03-07-06



Edwards Lifesciences

MyxoLogix Mitral Annuloplasty Ring

Model 5100

(Sizes: 26mm – 36mm)

First Human Use Approval Sheet

DHF# 6994

The signatures below indicate approval for "First Human Use" of the MyxoLogix mitral annuloplasty ring without holder.

Management Approvals:

(b)(6); (b)(4)

R&D

(b)(6); (b)(4)

Regulatory

(b)(6); (b)(4)

Quality

(b)(6); (b)(4)

Marketing

(b)(6); (b)(4)

Manufacturing Engineering

(b)(6); (b)(4)

R&D

(b)(6); (b)(4)

(b)(6); (b)(4)

3/3/06

3/6/06

03/06/06

3/3/06

3/6/06

3/6/06

Design Requirements Document

Myxo – Logix Annuloplasty Ring, Model 5100

DHF #6994

Rev. B

January 10, 2006

Approvals:

Research and Development:

(b)(6); (b)(4)

(b)(6); (b)(4)

EW Staff Engineer

Date:

1/10/06

Quality Engineer:

(b)(6); (b)(4)

(b)(6); (b)(4)

Quality Engineer

Date:

1/10/06

Regulatory Affairs:

(b)(6); (b)(4)

(b)(6); (b)(4)

Regulatory Affairs Associate III

Date:

1/11/06

Marketing:

(b)(6); (b)(4)

(b)(6); (b)(4)

Product Manager

Date:

1-10-06

Manufacturing Engineering:

(b)(6); (b)(4)

(b)(6); (b)(4)

EW Senior Engineer

Date:

01/10/06

Myxomatous Annuloplasty Ring, Model 5100

Design Input Elements:

1.0 OBJECTIVE/ SCOPE:

1.1 (b)(4)

2.0 USER/ PATIENT/ CLINICAL:

2.1 (b)(4)

2.2

2.3

2.4

3.0 PERFORMANCE CHARACTERISTICS:

The key technical objectives of this design are as follows:

3.1 (b)(4)

3.2

3.3

3.4

3.5

3.6

4.0 SAFETY:

4.1 (b)(4)

4.2

5.0 LIMITS/ TOLERANCES:

5.1 (b)(4)

6.0 RISK ANALYSIS:

6.1 (b)(4)

6.2

6.3

6.4

7.0 TOXICITY/ BIOCOMPATIBILITY:

7.1 (b)(4)

7.2

8.0 HUMAN FACTORS:

8.1 (b)(4)

8.2

8.3

9.0 PHYSICAL/ CHEMICAL:

9.1 (b)(4)

9.2

9.3

9.4

10.0 LABELING/ PACKAGING:

10.1 (b)(4)

10.2

11.0 RELIABILITY:

11.1 (b)(4)

11.2

11.3

12.0 STATUTORY/ REGULATORY:

12.1 (b)(4)

12.2

12.3 (b)(4)
12.4
12.5
12.6

13.0 INTERNAL/ EXTERNAL STANDARDS:

13.1 (b)(4)
13.2
13.3
13.4
13.5
13.6

14.0 MANUFACTURABILITY:

14.1 (b)(4)
14.2
14.3
14.4
14.5

15.0 STERILITY:

15.1 (b)(4)
15.2

16.0 COMPLAINT HISTORY:

16.1 (b)(4)

17.0 DESIGN HISTORY FILES:

17.1 (b)(4)

18.0 ENVIRONMENTAL COMPATIBILITY:

18.1 (b)(4)
18.2

19.0 COMPATIBLE DEVICES:

19.1 (b)(4)
19.2

| Line No. | Design Input (Customer Requirements) | Ref. | 2nd Tier Requirements | Design Output | DMR Reference | Verification Reference |
|----------|--------------------------------------|------|-----------------------|---------------|---------------|------------------------|
| 1 | Performance | | | | | |
| 2 | (b)(4) | | | | | |
| 3 | | | | | | |
| 4 | | | | | | |
| 5 | | | | | | |
| 6 | | | | | | |
| 7 | Implantation | | | | | |
| 8 | (b)(4) | | | | | |
| 9 | | | | | | |
| 10 | Sterilization | | | | | |

| Line No. | Design Input (Customer Requirements) | Ref. | 2nd Tier Requirements | Design Output | DMR Reference | Verification Reference |
|----------|--------------------------------------|------|-----------------------|---------------|---------------|------------------------|
| 11 | (b)(4) | | | | | |
| 12 | Biocompatibility | | | | | |
| 13 | (b)(4) | | | | | |
| 14 | | | | | | |
| 15 | Design for Manufacturing | | | | | |
| 16 | (b)(4) | | | | | |
| 17 | | | | | | |
| 18 | | | | | | |
| 19 | | | | | | |

| Line No. | Design Input (Customer Requirements) | Ref. | 2nd Tier Requirements | Design Output | DMR Reference | Verification Reference |
|----------|---|------|-----------------------|---------------|---------------|------------------------|
| 20 | (b)(4) | | | | | |
| 21 | Packaging | | | | | |
| 22 | (b)(4) | | | | | |
| 23 | Labeling | | | | | |
| 24 | (b)(4) | | | | | |
| 25 | Shelf Life | | | | | |
| 26 | (b)(4) | | | | | |
| 27 | Sizer | | | | | |
| 28 | (b)(4) | | | | | |
| 29 | | | | | | |
| 30 | | | | | | |

| | | |
|--|--|---|
| IRB Review - Office Use Only Northwestern University Institutional Review Board IRB #: <u>1532-004</u> APPROVED: <u>07/17/2007</u> <i>DLJ</i> | IRB Date Stamp - Office Use Only RECEIVED JUL 17 2007 OPRS | IRB Accession Number <u>200707-0908</u> Office Use Only IRB Project Number: 1532-004 |
|--|--|---|

Northwestern University – Office for the Protection of Research Subjects

Project Termination/Closure Form (Also use for studies that were never initiated)

Instructions: Please refer to the Termination Guidelines on when to terminate a project.

http://www.northwestern.edu/research/OPRS/irb/handbook/guidance/termination_guidelines.doc The Principal Investigator must sign this termination report. If this project involves the Robert H. Lurie Cancer Center, please give a copy of this report to the Clinical Research Director. If this project is conducted at RIC, please give a copy of this report to the Research Office.

Forward this submission to **OPRS, Rubloff, 7th Floor, 750 N. Lake Shore Drive, Chicago, IL 60611 or Hogan, G100-6th Floor, 2205 Tech Drive, Evanston, IL 60208**

Handwritten forms will not be accepted.

| | | |
|---|--|--|
| 1. Date of Preparation: 7/13/2007 | Date project is to be Terminated: 7/12/2007 | Northwestern IRB Chicago, IL EI: 8/8/08 LH Exhibit # 15 Page 1 of 2 |
| 2. Principal Investigator Name: McCarthy, Patrick MD | Telephone Number: 312-695-3114 Fax Number: 5-1903 E-Mail Address: <u>pmccart@nmh.org</u> | |
| Submission Prepared By: (b) (6) RN | Phone 5-4067 Fax 5-6854 E-Mail: (b) (6) @nmh.org | |
| 4. Project Title: Mitral Valve Pathology: A Quantitative Assessment Pre- and Post-Repair. | | |

5. Project Status:¹

A. Determined by Investigator (Check appropriate box (s) describing project status)

1. Project is completed—No Further Contact with Human Subjects is planned: no subjects are, or will be, treated or followed; all data are gathered and analyzed; and there are no further sponsor reports or publications to submit to the IRB.
2. Project terminated by the investigator: Reason:
3. Project terminated by the sponsor. If by the sponsor, please attach documentation.
4. Project Never Initiated--No human subjects were recruited. Work will not be done at this time.
5. OPRS Initiated Closure
6. Other: Give Reason(s):

B. Summary: Please attach a summary of your research findings written in lay language to aid the IRB in their review. Attach available research analysis, or reprints, include an overview of any recent literature, amendments or modifications of the research since the last full board review, reports from multi-center trials, Data Safety Committee reports, and any other relevant information. Also include information about findings (either good or bad) that should be disclosed to subjects in the study. Discuss the rationale for and method of notification to subjects. If the project was never initiated please explain why. **An abstract (attached) with project findings was submitted to the Society of Thoracic Surgery (STS); unfortunately it was not accepted.**

6. Enrolled Subjects:²

A. Total number of subjects/sample/charts approved for enrollment/to be studied in this project: **125**

B. Total number of subjects/samples/charts enrolled/studied to date: **25**

C. Have any subjects withdrawn from the study?: No Yes, Please explain on a separate sheet the reasons for withdrawal—give the subject initials, date enrolled, reason for withdrawal, and any other additional information. Reasons for withdrawal might include but not be limited to, lost to follow-up, moved from this area, serious adverse events, and non-compliance on the part of the subject.

D. Is there a fully executed consent form in the study file for each subject reported in 6B? Yes No, Please explain on a separate sheet. **N/A: Medical Record Review; Waiver of Consent granted**

E. Were more subjects enrolled than were IRB approved? No Yes, Please explain on a separate sheet.

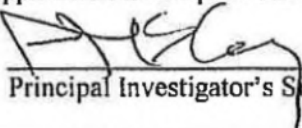
¹ All pending issues must be resolved prior to closure of the project.

² Enrolled subjects are those who signed consent forms and are participating in (or completed) the study. (Participating = e.g., filling out questionnaires, answering questions, taking drugs, having surgery, being called on the telephone, having data collected.) Enrollment is a finite number usually dictated by the sponsor or by statistical methods.

7. **Serious Adverse Events:** Have anticipated or unanticipated, serious or fatal adverse event(s) occurred?
 No Yes, Please provide a final summary of all Serious Adverse Events for this project.

8. **Protocol Violations/Monitor Reports:** Please attach any protocol violations/deviations or monitor reports that have not been previously submitted to the IRB. None

9. **External Audits:** Has this project been audited by the FDA, DHHS, a sponsor or other external independent auditor?
 No
 Yes, provide a copy of all correspondence related to any audits and any applicable audit reports. (Do not include routine monitor reports.)

10. **Investigator/Faculty Advisor Assurance:**
Investigator's Assurance:
I certify that the information provided in this application is complete and accurate.
Patrick M. McCarthy, MD  7/12/2007
Principal Investigator's Name Principal Investigator's Signature Date

11. **VA Endorsement:**

VA ACOS Research and Development Name and Signature (if applicable) Date

Please return completed form to: **The Office for the Protection of Research Subjects (OPRS)**
E-Mail: irb@northwestern.edu Website: <http://www.northwestern.edu/research/OPRS>

Chicago Campus
Rubloff, 7th Floor, 750 N. Lake Shore Drive, Chicago, IL 60611
Telephone: (312) 503-9338 Fax: (312) 503-0555

Or

Evanston Campus
Hogan, G100-6th Floor, 2205 Tech Drive, Evanston, IL 60208
Telephone: (847) 467-1723 Fax: (847) 467-3112

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 15
Page 2 of 2

Tasha Osafo

From: Tasha Osafo [t-osafo@northwestern.edu]
Sent: Thursday, July 12, 2007 2:50 PM
To: 'pmccart@nmh.org'
Subject: FW: IRB Project 1532-004

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University

Rubloff Building,
750 North Lake Shore Drive
Suite 700

Chicago, IL 60611

Phone: 312-503-4225

Fax: 312-503-0555

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

From: Tasha Osafo [mailto:t-osafo@northwestern.edu]

Sent: Thursday, July 12, 2007 2:48 PM

To: (b) (6)

Subject: RE: IRB Project 1532-004

(b) (6)

Since you wish to terminate this, I am going to officially withdraw your continuing review submission in our records. Please be sure to complete the Termination Form which is found at <http://www.research.northwestern.edu/research/oprs/irb/forms/docs/Termination.doc>

Thank you,

Tasha

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University

Rubloff Building,
750 North Lake Shore Drive
Suite 700

Chicago, IL 60611

Phone: 312-503-4225

Fax: 312-503-0555

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

From: (b) (6) [mailto:(b) (6) @nmh.org]

Sent: Thursday, July 12, 2007 2:02 PM

To: Tasha Osafo

Subject: RE: IRB Project 1532-004

Hi Tasha,

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 14
Page) of 4

I apologize for the delay in response, (b) (6). After further consideration, we have decided to terminate this project. No further research has been done since the project expiration (June 27). I will forward the project termination to your attention once completed. Please let me know if you have any questions.

Regards,

(b) (6)

(b) (6) RN, BSN, CCRC

Research Design Manager

Clinical Trials Unit

Bluhm Cardiovascular Institute

Northwestern University

676 N. St. Clair, Suite 1700

Chicago, IL 60611-2969

Ph: (b) (6)

Fax:

(b) (6) @nmh.org

"To learn more about the Bluhm Cardiovascular Institute, please visit our web site at <http://www.nmff.org/clinicaldepts/department.asp?id=66/>"

From: Tasha Osafo [mailto:t-osafo@northwestern.edu]
Sent: Thursday, June 28, 2007 6:01 PM
To: (b) (6) @northwestern.edu; McCarthy, Patrick M.D.
Subject: FW: IRB Project 1532-004

Dear (b) (6)

I'm writing to remind you that we have not yet received a response to the issues below.

Also, this project expired on June 27. As such, please understand that all study procedures must stop until approval is granted.

Thank you,

Tasha

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University
Rubloff Building,
750 North Lake Shore Drive
Suite 700
Chicago, IL 60611
Phone: 312-503-4225
Fax: 312-503-0555

Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 14
Page 2 of 4

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

From: Tasha Osafo [mailto:t-osafo@northwestern.edu]

Sent: Tuesday, June 19, 2007 11:15 AM

To: (b) (6) @northwestern.edu'

Cc: 'pmccart@nmh.org'

Subject: IRB Project 1532-004

Dear (b) (6)

We have received the Continuing Review of Research Form (CRRF) for Dr. McCarthy's project 1532-004, "Mitral Valve Pathology: A Quantitative Assessment Pre and Post Repair".

The study has undergone expedited review and was considered incomplete. The reviewer noted that the PI was approved to conduct a retrospective chart review of records from April 2004 through June 2006. As the PI now wishes to expand the dates of the chart review to May 2007, the study is no longer considered retrospective but prospective in nature. This point, as well as the change of dates needs to be documented in several forms of which I have outlined below. Until we receive these forms, this submission is considered **incomplete** ..

1. **Waiver of Authorization Form:**
 - a. Please submit an updated HIPAA Waiver of Authorization Form which reflects the expansion of the chart review to May 2007.
 - b. Please clarify that the study is no longer retrospective, but now prospective in nature. As a reference, attached is a PDF of the version we currently have on record.
2. **Waiver of Consent Form:** The waiver of consent initially granted for this study was only for the review of data in the records from April 2004 through June 2006. Please complete the waiver of consent form and clarify why a waiver of consent is needed for this change to the study. The form is available at <http://www.research.northwestern.edu/research/oprs/irb/informedConsent/docs/waiveConsent>
3. **Protocol:**
 - a. Please submit an updated study protocol which reflects the expansion of the chart review to May 2007 and
 - b. Please revise the protocol to indicate this study is no longer retrospective in nature, but prospective. I have attached a copy of the last approved protocol for your reference.
4. **CRRF:**
 - a. Please revise Section 7 to indicate that this is now a prospective study. Currently, the 1st sentence of the 2nd paragraph states that this is a retrospective study.
 - b. Please note that your study expires on June 27, 2007. Your response is needed by then to avoid a lapsed protocol. If you cannot respond by then, please be sure to complete Section 8.1 of the CRRF

Please feel free to contact me with any questions. I suggest responding to me via e-mail for the fastest response.

Thank you,

Tasha

Tasha K Osafo
Sr. IRB Coordinator Expedited/Periodic Review
Office for the Protection of Research Subjects
Northwestern University
 Rubloff Building,
 750 North Lake Shore Drive
 Suite 700

Northwestern IRB
 Chicago, IL
 EI: 8/8/08
 LH
 Exhibit # 14
 Page 3 of 4

Chicago, IL 60611

Phone: 312-503-4225

Fax: 312-503-0555

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Northwestern IRB
Chicago, IL
EI: 8/8/08
LH
Exhibit # 14
Page 4 of 4

7/12/2007

From: Wilkie, Robert L., Jr.
Sent: Thu, 19 Mar 2020 17:20:41 +0000
To: RLW
Subject: FW: Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States

From: (b)(6)
Sent: Thursday, March 19, 2020 1:20:15 PM (UTC-05:00) Eastern Time (US & Canada)
To: (b)(6)@fda.hhs.gov; (b)(6)@HHS.gov; (b)(6)@hhs.gov; Wilkie, Robert L., Jr.; (b)(6)@who.eop.gov; (b)(6)@fda.hhs.gov
Cc: (b)(6)
Subject: [EXTERNAL] Re: Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States

<https://www.irb.northwestern.edu/reportable-new-information-2/>

Reportable New Information (RNI) – Institutional Review Board (IRB) Office

Before You Begin. Review the guidance for New Information Reporting. Submissions that do not fit within these guidelines will be returned to the submission preparer without review. Provide details of the event you are submitting to the IRB, the actions taken to resolve the incident, and how this type of incident will be prevented in the future.

www.irb.northwestern.edu

Unanticipated Adverse Device Effect: Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

From: (b)(6)@sacredcardiology.com>
Sent: Thursday, March 19, 2020 10:51 AM
To: Fauci, Anthony (NIH/NIAID) [E] (b)(6)@niaid.nih.gov>; (b)(6)@nih.gov
(b)(6)@nih.gov>; (b)(6)@fda.hhs.gov <(b)(6)@fda.hhs.gov>; (b)(6)@HHS.gov <(b)(6)@HHS.gov>; (b)(6)@hhs.gov <(b)(6)@hhs.gov>; (b)(6)@va.gov <(b)(6)@va.gov>; (b)(6)@va.gov <(b)(6)@va.gov>; (b)(6)@who.eop.gov <(b)(6)@who.eop.gov>; (b)(6)@fda.hhs.gov>; (b)(6)@fda.hhs.gov <(b)(6)@fda.hhs.gov>
Cc: (b)(6)@gmail.com>; (b)(6)@sacredcardiology.com>
Subject: Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States

3-19-2020

Dear President Trump, Vice President Pence, Dr. Fauci, Dr. Hahn, Secretary Azar, and Mr. Wilkie,

I am writing to you as an ARRA investigator and a VA physician at the time of two unauthorized clinical trials performed in the US hospital without patient consent.

Several patients have died during the trial and after the trial, without consent and without FDA oversight.

I have reported these events to the FDA since July 2008 and as recently as March 9, 2020 at 11:00 am Central time.

The reporting was recorded by CBS in MN and the FDA press office has not responded to the press nor to the patients who still do not know that they were experimented on by a device company and the inventor who failed the patients despite a cease and desist order by the University IRB to stop the prospective clinical trial for the Myxo device.

At a time, when the lives of Americans are at risk from exposure to the virus, patients were exposed to illegal heart devices for several years. These patients have died as of recently. I spoke to the VA in Chicago and they have agreed it is time to report to the VA as well as the NIH who funded the registry, and the FDA, who confirmed that the devices were experimental, and HHS who funded the illegal trials using medicare insurance to pay for the surgeries.

The Federal Wide Assurance 1549 requires a five day reporting to the patients once heart attacks, deaths etc continue even years after the illegal clinical trial.

I hope you respond to these requests as a VA physician who worked at the Jesse Brown VA and the Lakeside VA and Northwestern during the illegal clinical trials to help the innocent victims who still do not know that the device was placed in their hearts without consent and without FDA authorization.

The delays by the FDA device section are worrisome, and I hope that Commissioner Hahn will take the leadership role to move forward to help these victims.

(b)(6) MD

Attaching the death reports

William Maisel testimony to Congress

VA Proficiency reports

Northwestern Federal Contract terminating the study

<https://www.kimt.com/content/news/Doctor-Faulty-device-implanted-in-hundreds-of-patients-without-consent-568682191.html>

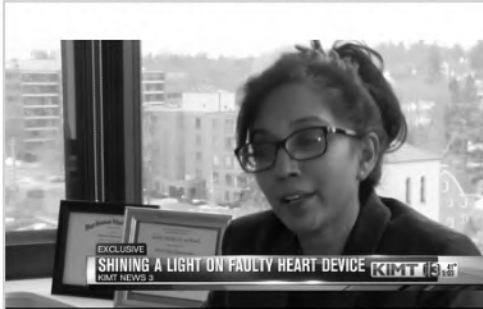


Doctor: Faulty device implanted in hundreds of patients without consent

ROCHESTER, Minn. - A Mayo Clinic trained physician is shining a light on a faulty prototype device that was sewn into patient's hearts without their consent. It may be hard to imagine but that's the reality for more than 700 patients who received surgery to fix leaky heart valves at Northwestern ...

www.kimt.com

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<https://www.irb.northwestern.edu/writing-an-effective-corrective-action-plan/>

Corrective and Preventive Action (CAPA) Plans – Institutional Review Board (IRB) Office

In the course of conducting research even the most experienced and diligent research teams deviate from the approved protocol or experience unexpected events.

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The IRB has not responded to my recent request for help for the victims.

From: Wilkie, Robert L., Jr.
Sent: Thu, 19 Mar 2020 18:32:12 +0000
To: RLW
Subject: FW: Response RE: Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States
Attachments: paper_ring_Highlighted_problems_Model 5100.pdf, IMR_Manuscript_Circ_06.pdf

From: (b)(6)
Sent: Thursday, March 19, 2020 2:30:41 PM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Cc: (b)(6)
Subject: [EXTERNAL] Fw: Response RE: Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States

Thank you for your email, I have been reporting these facts for over 13 years, and I was an eye-witness while I worked for the VA Lakeside and then the VA West side.

I called the VA today and they recommended I report since the VA funds the training of physicians in the Cardiology program at Northwestern University.

The other VA doctor who participated in the two research protocols is listed as a co-author on the two illegal clinical trials.

The VA sponsored many of the research protocols to cover-up the enrollment of patients and the failure to educate the physicians correctly in the treatment of the severe adverse events in order to conceal the evidence from the FDA.

Both of the attached trials were performed by VA funded physicians and Northwestern University IRB is not helping the patients, the Veterans etc who may have been enrolled in these studies.

(b)(6), MD

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This is the tip of the iceberg for the cover-up of the testing of patients.

(b)(6) MD

This repository should be placed on an immediate hold by the VA.

<https://www.feinberg.northwestern.edu/sites/bcvi-ctu/investigator-services/data-repository.html>

From: SECVA Inquiry (b)(6)@va.gov>

Sent: Thursday, March 19, 2020 12:23 PM

To: (b)(6)@sacredcardiology.com>

Subject: Response RE: Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States

Good afternoon Dr. (b)(6)

The Secretary has received your email dated March 19, 2020. He has forwarded your inquiry to Veterans Health Administration leadership for review and direct feedback, and someone will contact you regarding the investigation findings. Thank you for your communication.

**Please note that this email address does not accept replies.

Office of the Secretary
Department of Veterans Affairs
810 Vermont Ave NW
Washington DC 20420

From: (b)(6)@sacredcardiology.com>
Sent: Thursday, March 19, 2020 11:52 AM
To: Fauci, Anthony (NIH/NIAID) [E] (b)(6)@niaid.nih.gov>; (b)(6)@nih.gov;
(b)(6)@fda.hhs.gov; (b)(6)@HHS.gov; (b)(6)@hhs.gov; Wilkie, Robert L., Jr.
(b)(6)@va.gov>; (b)(6)@va.gov; (b)(6)@who.eop.gov; (b)(6)
<(b)(6)@fda.hhs.gov>; (b)(6)@fda.hhs.gov
Cc: (b)(6)@gmail.com>; (b)(6)
(b)(6)@sacredcardiology.com>
Subject: [EXTERNAL] Day Nine of Reporting regarding deaths related to illegal clinical trials in the United States

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| | |
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www.irb.northwestern.edu

The IRB has not responded to my recent request for help for the victims.

Initial clinical experience with Myxo-ETlogix* mitral valve repair ring

P. M. McCarthy, MD,^a E. C. McGee, MD,^a V. H. Rigolin, MD,^b Q. Zhao, MD,^b H. Subačius, MA,^c A. L. Huskin, RN,^c S. Underwood, RN,^a B. J. Kane, RDCS,^b I. Mikati, MD,^b G. Gang, MD,^a and R. O. Bonow, MD^b

Objective: Complexity of mitral valve repair for myxomatous disease has led to low adoption. We report initial experience with a new ring designed specifically for myxomatous disease, the Myxo-ETlogix (Edwards Lifesciences LLC, Irvine, Calif).

Methods: From March 15, 2006, through November 19, 2007, 129 patients underwent mitral valve surgery for pure myxomatous disease, and 124 valves (96.1%) were repaired. The Myxo-ETlogix ring was used in 100 cases and the Physio ring (Edwards) in 24. The Myxo-ETlogix design includes a 3-dimensional shape to reduce systolic anterior motion and a larger orifice to accommodate elongated leaflets and decrease need for sliding plasty. Direct mitral valve measurements were made. Sizing was based on A2 height, and choice of ring type was based on unresected leaflet heights.

Results: There was no operative mortality or lasting perioperative morbidity. The Myxo-ETlogix group had taller A2, P1, P2, and P3 leaflet segments than the Physio group ($P \leq .003$). Only 1 sliding plasty was performed for asymmetry in the Myxo-ETlogix group. Pre-discharge and follow-up echocardiograms ($n = 338$ in 124 patients) disclosed transient nonobstructive chordal systolic anterior motion in 3 echocardiograms in 3 patients. No patients had 2+ or greater mitral regurgitation. At discharge, 5.7% had 1+ mitral regurgitation; this proportion was 17.3% at last follow-up (mean 6.1 ± 4.4 months).

Conclusion: In initial experience with the Myxo-ETlogix ring, nonobstructive systolic anterior motion has been rare and obstructive systolic anterior motion not observed. Ongoing prospective echocardiographic and clinical studies will elucidate the role of this etiology-specific ring.

From the Bluhm Cardiovascular Institute, Division of Cardiothoracic Surgery,^a Cardiology,^b and Clinical Trials Unit,^c Northwestern Memorial Hospital, Chicago, Ill.

Read in part at the Eighty-seventh Annual Meeting of The American Association for Thoracic Surgery, Washington, DC, May 5–9, 2007.

P.M.M. is the inventor of the Myxo-ETlogix ring and receives royalties. R.O.B. and P.M.M. are consultants for Edwards Lifesciences LLC.

*Myxo-ETlogix is a trade name of Edwards Lifesciences LLC, Irvine, Calif.

Received for publication June 15, 2007; revisions received Dec 21, 2007; accepted for publication Feb 12, 2008.

Address for reprints: Patrick M. McCarthy, MD, Northwestern University, Division of Cardiothoracic Surgery, 201 E Huron St, Suite 11-140, Chicago, IL 60611-2908 (E-mail: pmccart@nmh.org).

J Thorac Cardiovasc Surg 2008;136:73-81
0022-5223/\$34.00

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doi:10.1016/j.jtcvs.2008.02.013

Mitral valve (MV) prolapse is common, occurring in 1% to 2.5% of the population.¹ Myxomatous mitral regurgitation (MR) is characterized by elongation and thickening of the valve leaflets with annular and dilatation prolapse (Carpentier type II).² Numerous studies have demonstrated that mitral repair generally gives a more favorable result than does MV replacement, but because of the complexity of the pathology and therefore the procedure required, it is performed in fewer than 50% of cases according to data from the United States and Europe.³⁻⁶ Furthermore, the considerable interpatient variability has required the surgeon to approach valve repair as an art, and valve repair has been concentrated such that a minority of surgeons perform the majority of repairs. Consequently, it has been difficult for a low- or medium-volume mitral repair surgeon to develop the numerous skills necessary for successful repair, considering the wide variety of surgical techniques that may be required for complex repairs.

An additional repair problem specific to myxomatous disease is the development of systolic anterior motion (SAM), which has been reported in 2% to 16% of patients after mitral repair.⁷⁻¹⁰ Transient SAM may be seen during first weaning from cardiopulmonary bypass and may be easily treated by volume infusion from the pump to increase the systemic blood pressure (afterload) if the patient is hypotensive and vasodilated and by stopping positive inotropes. More troublesome is persistent SAM, which may require additional medical or surgical therapy. SAM is precipitated by

Abbreviations and Acronyms

MR = mitral regurgitation
 MV = mitral valve
 SAM = systolic anterior motion

elongated leaflets and may cause left ventricular outflow tract obstruction and residual or recurrent MR. SAM may be caused by a short distance between the point of leaflet coaptation to the nearest point on the ventricular septum, which may be seen when the posterior leaflet is too tall or the annuloplasty ring placed is too small.^{7,8} An elongated anterior leaflet may also contribute to SAM, and numerous techniques can be used to avoid or eliminate SAM, such as shortening the anterior leaflet, creating a double orifice (edge-to-edge approximation), or even myectomy.^{2,11-16} Reducing the height of the posterior leaflet (sliding plasty) is the most common technique.^{2,10,17} Although some would argue that SAM may be managed medically with long-term β -blocker therapy and a low late need for reoperation, persistent SAM may be associated with continuing MR, and a young patient requiring long-term β -blocker therapy has had an imperfect operation.^{18,19} In an age when surgery is being performed early, in symptom-free patients, this result is less than ideal.¹ Ideally, the repair procedure would avoid SAM altogether and not require long-term medical management.

We sought to develop a new MV repair ring designed to accommodate the specific pathologic conditions of myxomatous disease. This etiology-specific ring, the Myxo-ETlogix (Edwards Lifesciences LLC, Irvine, Calif) ring has a larger orifice than does a Physio (Edwards Lifesciences) ring (which is based on normal anatomy) to accommodate the elongated leaflets. It also has a 3-dimensional shape that moves the coaptation point away from the septum (increasing the distance between the point of leaflet coaptation to the nearest point on the ventricular septum), thereby reducing the risk of SAM.^{8,14} Because this etiology-specific ring has a larger orifice, a secondary advantage would be that extensive leaflet reconstruction to reduce the size of the leaflets back to “normal” (sliding plasty) would not be needed, or at least would be needed much less frequently. This would reduce the complexity of myxomatous valve repair and ideally make it more generalizable. Furthermore, the larger orifice leads to a low or normal gradient. This is the first report of the concepts behind the new Myxo-ETlogix, the impact that it had on our use of other mitral repair rings and techniques, and the initial clinical results.

Materials and Methods**Patient Characteristics**

Patient information and follow-up data were obtained from the prospectively maintained cardiac surgery outcomes registry of the

Bluhm Cardiovascular Institute, which was approved by the Northwestern University Institutional Review Board for use in research. The study ran from the date of first use of Myxo-ETlogix (March 15, 2006) until the date of 100th Myxo-ETlogix implant (November 19, 2007). For the purposes of this study, we analyzed only those patients with MR caused by isolated myxomatous degenerative MV disease ($n = 129$). The diagnosis of myxomatous disease was determined by echocardiographic and surgical findings of elongated MV leaflets with prolapse (type II). Patients were excluded if they had rheumatic valve disease, ischemic valve disease, cardiomyopathy, endocarditis, or mixed pathology. Among the 129 myxomatous MR cases, MV repair was performed in 124 patients (96.1%), and MV replacement was performed in 5 patients (3.9%). These 5 patients had ages of 65, 72, 74, 78, and 84 years, and all had annular and leaflet

cificiation. Patients included in this analysis were operated on by two surgeons at a single institution, Northwestern Memorial Hospital.

In the repair group, 100 patients received the Myxo-ETlogix annuloplasty ring, which is a Food and Drug Administration–approved for patients undergoing MV repair. During the same period, the Carpentier–Edwards Physio ring was used to repair 24 valves in patients with myxomatous MV disease. Thus 80.6% of the patients with myxomatous disease underwent repair with the Myxo-ETlogix ring, and 19.4% underwent repair with a Physio ring. According to our practice, all patients in the group were prospectively followed up by a specific valve nurse who was available to answer patient questions, arrange follow-up visits, and facilitate entry into prospective 3-dimensional echocardiographic and other imaging studies. The characteristics of the patients who received the Myxo-ETlogix ring are compared with those of the patients who received a Physio ring in Table 1. Overall, the age of the patients was 57 ± 13 years, and the Myxo-ETlogix patients were younger ($P = .047$). The Myxo-ETlogix patients had more MR (97% with 4+, $P < .001$). Other significant differences between the groups included smaller body mass index and more white patients in the Myxo-ETlogix group (patient self-report), whereas patients in the Physio group were more likely to have chronic obstructive pulmonary disease. The 5 patients who underwent MV replacement were significantly older than the 124 repair patients ($P < .001$), and their operative findings precluded safe, durable MV repair. All these patients underwent valve replacement with a bioprosthetic bovine pericardial valve. In keeping with the trend toward early repair in patients with myxomatous MV disease, most of the patients in the repair group were in New York Heart Association functional class I or II (81.4%).

Characteristics of the Myxo-ETlogix Ring

The Myxo-ETlogix ring was designed as a complete annular remodeling ring with etiology-specific variations from the Physio ring (Figure 1).²⁰ The anteroposterior dimension of the ring was increased 29% to accommodate elongated myxomatous leaflets. Depending on the exact size of the ring, this led to an increase in anteroposterior diameter of 5 to 8 mm, designed to correspond to typical reduction in posterior leaflet height in patients who undergo sliding plasty. Rather than the surgeon performing extensive reconstruction to reduce the height of the posterior leaflet by 5 to 8 mm, instead the ring pulls the posterior leaflet down by a corresponding amount. This also creates a 16% increase in the total orifice area for the Myxo-ETlogix ring. The largest anteroposterior diameter of a size 40 Physio ring is 27.2 mm, which corresponds most closely to a size 32 Myxo-ETlogix ring (28.0 mm). A size 40 Myxo-ETlogix

TABLE 1. Preoperative patient characteristics by annuloplasty type

| | Total (N = 124) | Physio (n = 24) | Myxo-ETlogix (n = 100) | P value |
|---|-----------------|-----------------|------------------------|---------|
| Age (y) | | | | .047* |
| Mean ± SD | 57.4 ± 13.4 | 62.2 ± 12.1 | 56.2 ± 13.5 | |
| Range | 22–85 | 41–81 | 22–85 | |
| Male (No.) | 76 (61.2%) | 14 (58.3%) | 62 (62.0%) | NS |
| Body mass index (kg/m ²) | | | | .006† |
| Mean ± SD | 25.4 ± 4.5 | 27.6 ± 3.9 | 24.9 ± 4.5 | |
| Range | 15.1–39.5 | 20.2–34.2 | 15.1–39.5 | |
| White race (No.) | 103 (83.1%) | 16 (66.7%) | 87 (87.0%) | .017 |
| Previous cardiac surgery (No.) | 1 (0.8%) | 0 (0.0%) | 1 (1.0%) | NS |
| Comorbidities (No.) | | | | |
| Previous myocardial infarction | 2 (1.6%) | 1 (4.2%) | 1 (1.0%) | NS |
| Congestive heart failure | 16 (12.9%) | 5 (20.8%) | 11 (11.0%) | NS |
| Coronary artery disease | 19 (15.3%) | 4 (16.7%) | 15 (15.0%) | NS |
| Diabetes | 3 (2.4%) | 0 (0.0%) | 3 (3.0%) | NS |
| Hypertension (systemic) | 48 (38.7%) | 13 (54.2%) | 35 (35.0%) | .083 |
| Hypertension (pulmonary) | 65 (52.9%) | 13 (54.2%) | 52 (52.0%) | NS |
| Renal failure | 0 (0.0%) | 0 (0.0) | 0 (0.0) | NS |
| Chronic obstructive pulmonary disease | 8 (6.5%) | 4 (16.7%) | 4 (4.0%) | .045‡ |
| Hyperlipidemia | 40 (32.3%) | 9 (37.5%) | 31 (31.0%) | NS |
| Atrial fibrillation or flutter | 26 (21.0%) | 7 (29.2%) | 19 (19.0%) | NS |
| New York Heart Association functional class (No.) | | | | NS |
| I | 35 (28.2%) | 4 (16.7%) | 31 (31.0%) | |
| II | 66 (53.2%) | 13 (54.2%) | 53 (53.0%) | |
| III–IV | 23 (18.6%) | 7 (29.2%) | 16 (16.0%) | |
| Prolapse (No.) | | | | NS |
| Anterior | 8 (6.5%) | 2 (8.7%) | 6 (6.0%) | |
| Posterior | 83 (67.5%) | 19 (82.6%) | 64 (64.0%) | |
| Anterior and posterior | 32 (26.0%) | 2 (8.7%) | 30 (30.0%) | |
| Preoperative echocardiographic mitral regurgitation (No.) | | | | <.001 |
| 2+ | 2 (1.6%) | 2 (8.3%) | 0 (0.0%) | |
| 3+ | 7 (5.7%) | 4 (16.7%) | 3 (3.0%) | |
| 4+ | 115 (92.7%) | 18 (75.0%) | 97 (97.0%) | |
| LV ejection fraction (%) | | | | NS |
| Mean ± SD | 59.4% ± 7.5% | 60.7% ± 7.0% | 59.1% ± 7.6% | |
| Range | 35%–80% | 50%–80% | 35%–75% | |
| LV end-systolic dimension (cm) | | | | NS |
| Mean ± SD | 3.6 ± 0.6 | 3.6 ± 0.6 | 3.6 ± 0.6 | |
| Range | 2.1–5.1 | 2.3–4.4 | 2.1–5.1 | |
| LV end-diastolic dimension (cm) | | | | NS |
| Mean ± SD | 5.5 ± 0.7 | 5.5 ± 0.6 | 5.5 ± 0.7 | |
| Range | 3.9–7.1 | 4.3–6.5 | 3.9–7.1 | |

NS, not significant ($P > .20$); LV, left ventricular. *Squared transformation. †Natural log transformation. ‡Fisher exact test.

ring has an anteroposterior diameter of 35.0 mm. The Myxo-ETlogix ring was only available in sizes 26 through 36 until mid November 2006, when sizes 38 and 40 became available but sizes 26 and 28 became unavailable. This shortage was due to production of a limited quantity of early rings.

In addition to accommodating the larger leaflets, the Myxo-ETlogix ring was designed to move the coaptation point down, and also away from the septum, by means of a 4-mm shape change centered at the P2 region, pulling the ring into the left atrium (Figure 1) and resulting in an increase in the distance between the point of leaflet coaptation to the nearest point on the ventricular septum. The net

effect of these two changes is to pull the coaptation point down and away from the septum.

Operative Techniques

Operative techniques were largely based on Carpentier’s time-tested concepts of resection of the prolapsing segment, chordal transfer if necessary, leaflet reconstruction, and complete remodeling annuloplasty ring.^{3,20} The Myxo-ETlogix ring was used for patients with elongated anterior leaflets or tall remaining posterior leaflet segments after resection. If the remaining posterior and anterior leaflets were normal after resection, then a Physio ring was used. Repair techniques

ACD

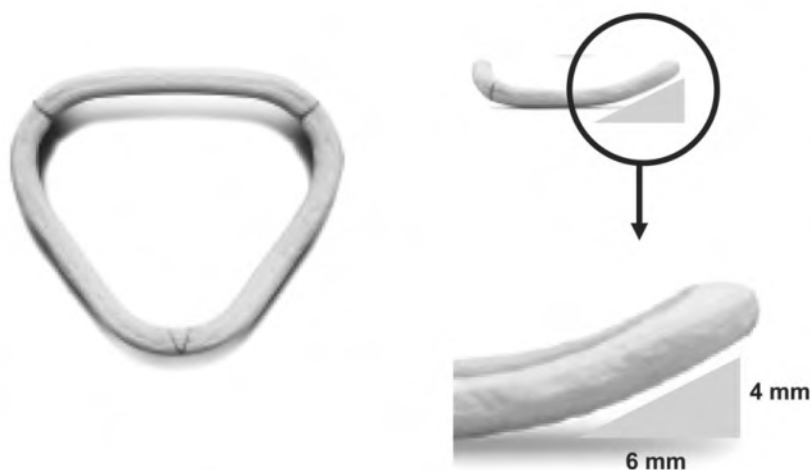


Figure 1. Myxo-ETlogix ring designed for patients with leaflet elongation historically treated with sliding plasty with risk of systolic anterior motion. Ring has longer anteroposterior diameter (typically 6 mm) to accommodate larger leaflets, corresponding to typical posterior leaflet height reduction from sliding plasty. P2 segment of ring has 4-mm displacement into annulus. Net effect of these two changes moves coaptation point down and away from septum, reducing risk of systolic anterior motion.

for both groups included leaflet resection, chordal transfer, commissuroplasty, and ring annuloplasty. No artificial chords were used in any patients. Before the Myxo-ETlogix ring was available, sliding annuloplasty was performed in 38% of cases of myxomatous disease (according to our database) when the remaining posterior segments were longer than 20 mm by visual inspection (not by direct measurement, which was not yet available) and sometimes when the posterior leaflet was shorter than 20 mm but there was a wide resection.

Concomitant cardiac surgical procedures (Table 2) included a maze procedure in 31 patients (25%), tricuspid valve annuloplasty in 12 patients (9.7%), coronary artery bypass grafting in 17 patients (13.7%), and aortic valve replacement in 3 patients (2.4%). There was no difference in concomitant procedures between the Physio and Myxo-ETlogix groups, but the ring size used in the Myxo-ETlogix group was larger ($P = .001$). The 1 patient (in the Myxo-ETlogix group) who underwent sliding plasty had an unresected remnant P2 height of 27 mm and a P3 height of 16 mm. Because of the extensive size discrepancy and a wide resection (22 mm), the height of the remaining P2 was reduced with a short sliding plasty. A second pump run was performed in 2 cases (1.6%) because of residual MR (1+–2+), with conversion from repair to replacement in an 84-year-old patient and successful additional leaflet repair in another patient.

Direct MV Measurements and Choice of Myxo-ETlogix Versus Physio Ring

Direct measurements of the MV were taken with a custom-designed set of measuring calipers. These distance measurements included commissure-to-commissure, trigone-to-trigone, and heights of the leaflet at P1, P2, P3, and A2 segments (Figure 2). Other measurements included width of the resected segment, width of the annulus after compression sutures, height of the middle segment of the posterior leaflet after reconstruction when applicable, and overlaps at P1, P2, P3, A1, A2, and A3. The results of these measurements are depicted in Figure 2. Table 3 compares the measures in patients with Myxo-ETlogix rings with those of patients with Physio rings. Measurements were available for 98 of 100 patients in the Myxo-ETlogix group and 22 of 24 patients in the Physio group.

Ring size was chosen according to A2 height. The measurement was referenced to a chart of the anteroposterior diameter of Myxo-

ETlogix and Physio rings. Ring size was true sized to A2 height in most cases. Occasionally, a larger Myxo-ETlogix ring was chosen because of an unusually tall (>20 mm) posterior leaflet, a smaller Myxo-ETlogix ring was chosen if there was a short posterior leaflet (<12 mm), or another size was chosen if the closest ring size was not available. Other measurements or judgments (commissure-to-commissure, trigone-to-trigone, anterior leaflet surface area) were not used for sizing.

The Physio ring was used for the subset of patients who had what Carpentier classifies as “fibroelastic deficiency.”²¹ This group tended to be older, with associated comorbidities such as hypertension and chronic obstructive pulmonary disease, and the pathologic characteristics typically consisted of ruptured chords at the P2 segment with normal lengths of P1, P3, and A2. The pathology at P2 was resected, and the remaining valve leaflet lengths were therefore normal, so the Physio ring was chosen as a design based on normal valve anatomy.¹⁰ Patients who received a Myxo-ETlogix ring consisted of those with Barlow disease and those with lengthening of unresected segments of the leaflet, the anterior leaflet, or both. Most patients did not fall into two distinct categories (Barlow disease vs fibroelastic deficiency) and instead had more intermediate leaflet length, as depicted in Figure 2.

Echocardiographic Techniques

MR was assessed as follows: none or trivial, 0; mild, 1+; moderate, 2+; moderate to severe, 3+; and severe, 4+. Nonobstructive (chordal) SAM was defined as anterior motion of the MV or subvalvular apparatus without an elevation of the peak velocity or a late peaking velocity profile in the Doppler waveforms in the left ventricle or left ventricular outflow tract. Echocardiography was performed in 100% of patients intraoperatively, at discharge, and, according to our usual practice, at approximately 1 month and between 3 and 6 months after surgery, annually, and any other time as clinically indicated.

Statistical Analysis

Demographic and clinical patient characteristics in the Physio and Myxo-ETlogix groups were compared with t tests for continuous variables and χ^2 tests for categorical variables. Group differences in intraoperative variables were evaluated with the same

TABLE 2. Operative results

| | Total (N = 124) | Physio (n = 24) | Myxo-ETlogix (n = 100) | P value |
|---|-----------------|-----------------|------------------------|---------|
| Ring size (mm) | | | | .001 |
| Mean ± SD | 33.0 ± 3.4 | 31.1 ± 2.6 | 33.5 ± 3.4 | |
| Range | 26–40 | 26–36 | 26–40 | |
| Resection (No.) | 110 (88.7%) | 20 (83.3%) | 90 (90.0%) | NS |
| Width of resection (mm) | | | | <.001 |
| Mean ± SD | 15.5 ± 6.4 | 11.3 ± 3.5 | 16.6 ± 6.5 | |
| Range | 7–36 | 7–20 | 7–36 | |
| Sliding plasty (No.) | 0 (0.8%) | 0 (0.0%) | 1 (1.0%) | NS |
| Chordal transfer (No.) | 20 (16.1%) | 1 (4.2%) | 19 (19.0%) | .119* |
| Crossclamp time (min) | | | | .195† |
| Mean ± SD | 88.1 ± 22.7 | 83.5 ± 24.1 | 89.2 ± 22.3 | |
| Range | 52–169 | 52–138 | 55–169 | |
| Cardiopulmonary bypass time (min) | | | | NS |
| Mean ± SD | 104.7 ± 26.1 | 101.0 ± 26.5 | 105.6 ± 26.0 | |
| Range | 67–190 | 67–159 | 67–190 | |
| Commissuroplasty (No.) | 7 (5.7%) | 0 (0.00%) | 7 (7.0%) | NS |
| Concomitant procedures (No.) | | | | |
| Coronary artery bypass grafting | 17 (13.7%) | 3 (12.5%) | 14 (14.0%) | NS |
| Atrial valve replacement | 3 (2.4%) | 0 (0.00%) | 3 (3.0%) | NS |
| Tricuspid valve annuloplasty | 12 (9.7%) | 1 (4.2%) | 11 (11.0%) | NS |
| Maze | 31 (25.0%) | 8 (33.3%) | 23 (23.0%) | NS |
| Postoperative | | | | |
| Mortality, infection, myocardial infarction, or acute renal failure (No.) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | NS |
| Reoperation for bleeding (No.) | 1 (0.8%) | 0 (0.0%) | 1 (1.0%) | NS |
| Cerebrovascular accident (No.) | 1 (0.8%) | 0 (0.0%) | 1 (1.0%) | NS |
| Hospital stay (d) | | | | NS |
| Mean ± SD | 5.8 ± 2.9 | 6.0 ± 2.6 | 5.6 ± 2.9 | |
| Range | 3–24 | 4–15 | 3–24 | |
| Intraoperative echocardiography | | | | |
| Mitral regurgitation (No.) | | | | NS |
| 0 | 121 (97.6%) | 23 (95.8%) | 98 (98.0%) | |
| 1+ | 3 (2.4%) | 1 (4.2%) | 2 (2.0%) | |
| Mean gradient (mm Hg) | | | | NS |
| Mean ± SD | 3.1 ± 1.5 | 3.3 ± 1.9 | 3.0 ± 1.4 | |
| Range | 0.6–10.0 | 1.4–10.0 | 0.6–9.0 | |
| Predischarge echocardiography | | | | |
| Mitral regurgitation (No.) | | | | NS |
| 0 | 115 (92.7%) | 23 (95.8%) | 92 (93.9%) | |
| 1+ | 7 (5.7%) | 1 (4.2%) | 6 (6.1%) | |
| Mean gradient (mm Hg) | | | | .134† |
| Mean ± SD | 3.3 ± 1.4 | 3.7 ± 1.7 | 3.2 ± 1.4 | |
| Range | 1.2–8.6 | 1.5–8.0 | 1.2–8.6 | |

NS, Not significant. *Fisher exact test. †Natural log transformation.

methodology. Continuous variables were appropriately transformed if a better approximation of normal distribution could be achieved. Fisher exact test was used for comparisons of categorical variables with a minimum cell count of 5 or less.

Results

Postoperative complications were low, with no deaths, no infections, no perioperative infarctions, 1 reoperation for bleeding (0.8%), and 1 stroke on postoperative day 3 from atrial

fibrillation that resolved before discharge. Follow-up was 100% complete, and there were no late deaths.

Predischarge and follow-up echocardiograms totaled 338. No MR or trivial MR was present at discharge in 92.7% of patients, and 1+ was present in 5.7% (Table 2). Mean gradient at discharge showed a trend toward being higher in the Physio group (3.7 ± 1.7 mm Hg vs 3.2 ± 1.4 mm Hg, P = .134, natural log transformation to normalize the data). At most recent follow-up (mean 6.1 ± 4.4 months)

ACD

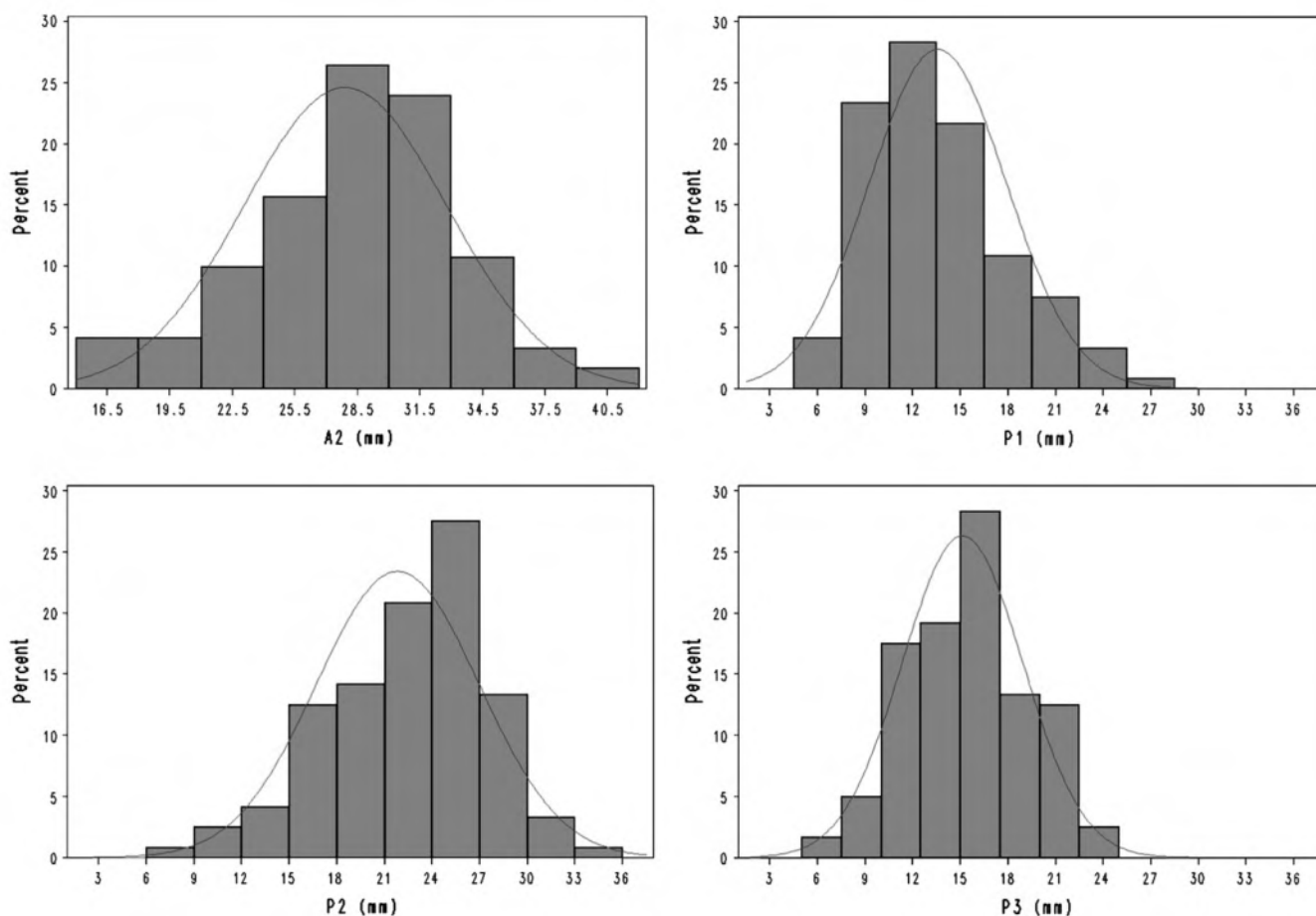


Figure 2. Direct measurement with custom calipers provided quantitative data on leaflet length in different segments documenting elongated leaflets in bell-shaped frequency curve. In particular, A2 height was very elongated; this was used to choose appropriate ring type (Physio ring vs Myxo-ETlogix ring) and ring size.

1+ MR was present in the Physio group in 1 patient (10%) and in the Myxo-ETlogix group in 16 patients (18%, differences from baseline and between groups not significant). There was no significant difference between MR at discharge and last follow-up. No patients had 2+ or greater MR.

After surgery, no obstructive SAM was seen, and nonobstructive chordal SAM was inconsistently seen in 3 patients. In 1 patient (with a 32-mm Myxo-ETlogix valve), SAM was first detected 14 days after discharge, but subsequent echocardiograms on days 82, 214, and 397 had negative results. In a second patient (with a 36-mm Myxo-ETlogix valve), there was no SAM early (pre-discharge or day 12 after discharge), SAM was recorded on day 160 after discharge, and at 1-year follow-up there was no SAM. In a third patient (with a 34-mm Physio ring), discharge echocardiography showed chordal SAM; this patient has not yet returned for follow-up. Transient intraoperative SAM shortly after weaning from bypass was uncommon (3 patients), depended on volume status and blood pressure, and never required a sec-

ond pump run or revision. One patient (with a 28-mm Myxo-ETlogix valve with commissuroplasty) had an early uneventful course after repair, with a low gradient (3.5 mm Hg), but had an intense, generalized inflammatory reaction, including both mitral leaflets, and required reoperative MV replacement for mitral stenosis 13 months after repair. Table 2 summarizes operative results for both groups.

Discussion

Overall, in an age of early repair for myxomatous disease, our results demonstrated a safe operation with low morbidity, a high rate of repair (96%), and excellent early results with little residual or recurrent MR (none at least 2+). We have found clinical benefit in precise anatomic measurement of the pathologic tissue, and these data drive our choice of ring size and type of ring prosthesis. This has led to predictable coaptation of the leaflets, without rings or residual leaflet heights we considered too small or too big. Our data indicate that although some patients' leaflets fall into the extremes of

TABLE 3. Direct preoperative and postoperative mitral valve measurements

| Measurement (mm) | Total | Physio (n = 22) | Myxo-ETlogix (n = 98) | P value |
|--------------------|------------|-----------------|-----------------------|---------|
| A2 | | | | <.001 |
| Mean ± SD | 27.9 ± 4.9 | 23.7 ± 5.2 | 28.9 ± 4.3 | |
| Range | 15-41 | 17-34 | 15-41 | |
| P1 | | | | <.001 |
| Mean ± SD | 13.6 ± 4.3 | 10.6 ± 2.9 | 14.3 ± 4.3 | |
| Range | 6-27 | 6-20 | 6-27 | |
| P2 | | | | .003 |
| Mean ± SD | 21.9 ± 5.1 | 19.0 ± 4.6 | 22.5 ± 5.0 | |
| Range | 7-34 | 9-30 | 7-34 | |
| P-middle* | | | | <.001 |
| Mean ± SD | 14.6 ± 2.9 | 12.3 ± 1.9 | 15.1 ± 2.8 | |
| Range | 8-23 | 10-16 | 8-23 | |
| P3 | | | | <.001 |
| Mean ± SD | 15.1 ± 3.8 | 12.5 ± 2.6 | 15.7 ± 3.8 | |
| Range | 6-24 | 8-18 | 6-24 | |
| Cusp-to cusp | | | | .007 |
| Mean ± SD | 38.1 ± 6.0 | 35.0 ± 4.3 | 38.8 ± 6.2 | |
| Range | 27-51 | 27-45 | 27-51 | |
| Trigone-to-trigone | | | | .023 |
| Mean ± SD | 24.6 ± 4.2 | 22.8 ± 3.4 | 25.0 ± 4.3 | |
| Range | 14-36 | 16-28 | 14-36 | |
| P2 overlap | | | | .003 |
| Mean ± SD | 6.5 ± 1.9 | 5.4 ± 1.4 | 6.8 ± 1.9 | |
| Range | 2-13 | 4-9 | 2-13 | |
| A2 overlap | | | | .070 |
| Mean ± SD | 5.7 ± 1.9 | 5.0 ± 1.6 | 5.8 ± 1.9 | |
| Range | 2-11 | 3-9 | 2-11 | |

*P-middle is the height of the leaflet after P2 resection and reconstruction.

Barlow disease versus fibroelastic deficiency, most patients' leaflet lengths fall somewhere between these extremes. Although an artistic, creative approach to complex valve problems with many different techniques is still valuable, we hope to move toward a more standardized, generalizable, reproducible repair that will lead to higher repair rates. Our current approach includes three steps: (1) trapezoidal resection (mean 15.5 ± 6.4 mm) of prolapsing posterior leaflet segments with chordal transfer to extensive anterior prolapsing segments if needed, (2) ring choice and sizing that is based on A2 and remaining posterior leaflet heights, and (3) complete remodeling annuloplasty with a Physio ring for normal remaining leaflets or with a Myxo-ETlogix ring for elongated leaflets. Although sliding plasty (and other complex techniques) should not be forgotten, in our institution we reduced the use of sliding plasty from 38% before this series to less than 1% in this experience. After reconstruction, the ratio of A2 height to posterior leaflet was 1.9 in both groups, which is thought to be optimal. Others routinely use resection without sliding plasty, but SAM does appear to be more common in those series than in ours (2.4% transient nonobstructive SAM and SAM without left ventricular outflow tract obstruction).^{18,22}

Quantitative data, other than from echocardiograms, have been hard to find in mitral repair series. Use of the Adams "ink test" and direct measurement of valve segments should help standardize our results and make it easier to compare results from different series.²³⁻²⁵ All these points are important, because we now see symptom-free patients for whom the guidelines recommend repair at experienced centers if there is a greater than 90% chance of repair without residual MR.^{1,24,25}

Large annuloplasty rings have been recommended for patients with Barlow disease.⁷ We agree that this is an important consideration, and more practical than bileaflet resection or reconstruction to reduce leaflet height. The new Myxo-ETlogix ring, designed for these patients, is significantly larger than existing commercial remodeling rings. Barlow disease is not a distinct entity in most cases, however, and even histologic studies have shown a large group of disorders intermediate between Barlow disease and fibroelastic deficiency.²¹ Whereas some surgeons may describe Barlow disease in 1% of patients, others may use that term to describe 50% of their patients with degenerative disease. Furthermore, our data show that some patients may have an elongated A2 segment but normal posterior segments, or vice versa. The

choice of a large ring thus is variable by surgeon. Although the average A2 height in our series (29 mm) corresponds most closely to a 34 Myxo-ETlogix ring, larger than the largest Physio ring (27 mm), we commonly used smaller Myxo-ETlogix rings instead of large Physio rings because of the perceived benefit of the 4-mm P2 displacement with the Myxo-ETlogix ring to reduce the risk of SAM. Whether it is the P2 displacement or the large size of the Myxo-ETlogix ring that accounts for our low incidence of SAM is not yet clear.

Study Limitations

This was a nonrandomized study of the initial use of a new commercially available ring, but not all ring sizes were available during the study period. The inventor of the ring was the surgeon in the vast majority of cases, and we attempted to reduce this bias with direct quantitative measurements and standard echocardiographic reporting. The data in all tables and figures therefore represent unbiased measurements and clinical results. A randomized trial is certainly feasible but would be best performed at another institution, albeit with experienced surgeons.

In summary, a new ring was introduced with a change in our clinical practice. The result was simpler MV repair procedures, rare nonobstructive SAM, and excellent clinical and echocardiographic results. Further confirmation at other centers is pending, and late echocardiographic follow-up is ongoing.

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Discussion

Dr Aidan A. Raney (*Newport Beach, Calif*). I enjoyed this presentation very much. Dr McCarthy is making a major contribution. As he mentioned, the reparability rate of valves in this country is in the

40% to 50% range. However, if the most complex valves with excessive tissue are included, the overall reparability rate is probably going to be significantly lower, maybe in the 30% range. This device is a tremendous advance. Not only does it simplify the procedure but it also reduces the risk of SAM.

When we looked at our series of over 200 patients about 1½ years ago, we also had about a 5% incidence of SAM that required a second pump run and correction.

I have a few questions for you. In your series, are you repairing all the myxomatous valves with the Myxo-ETlogix ring or do you have a sense of certain valve characteristics that would preclude using this device?

Dr McCarthy. Right now, we look at the leaflet and annulus size. In the majority of these patients with myxomatous leaflets, something is elongated. The valves do not always fall into that category of fibroelastic deficiency, so that it may be an elongated anterior leaflet but not a very elongated posterior, or the other way around. I use the Physio ring when the remaining valve is normal: the anterior leaflet, P1 and P3, are normal, and we have resected the abnormal part, which is usually a flail involving P2.

Dr Raney. Do you think that there is less modification of the annulus with this device, that is, without quadrangular resection and a plication of the posterior annulus? Because sizing can be a problem, do you think that transesophageal echocardiography before the repair will provide a good indication of what size of a Myxo-ETlogix ring to use?

Dr McCarthy. We are collecting a big database on our MV repairs, and we are also going to correlate it with what echocardiography measures. So far, it looks very good. When we measure A2 at 29 mm, the echocardiographer measures it at roughly the same. We hope to get to a point where the echocardiographer can identify the

height of the anterior and posterior leaflets and we can then prescribe the right sized ring.

Dr Raney. We have used this ring now in 8 cases, and I have been very impressed with the efficacy and the efficiency of the ring.

Dr Michael Mack (Dallas, Tex). Dr McCarthy, do you have any experience using this ring with artificial chords and does that make sense?

Dr McCarthy. I think it makes sense. I do not really use artificial chords very much. I am still pretty classic and I do chordal transfer. However, some surgeons are using artificial chords with the ring. If artificial chords are used on the posterior leaflet where there is an elongated P2 segment that is not being replaced, I think this would make sense, because otherwise, as you could see from the AP diameter, a 40-mm Physio ring is not nearly big enough for that group of patients.

Dr Mack. Is this ring generally available?

Dr McCarthy. It is in the United States now.

Dr Jen-Ping Chang (Kaohsiung, Taiwan). We all know that Professor Carpentier repairs the Barlow valves by banding the septal portion of the classic ring anteriorly, and we know your ring is just like bending the posterior portion of the ring posteriorly. What is the difference between the anterior displacement and the posterior displacement of this ring?

Dr McCarthy. The anterior displacement that Dr Carpentier does periodically is variable: he could bend it just a little bit or he could bend it quite a bit. It seemed to us most of the reduction should be more posterior rather than anterior, and so when we designed the ring, that is where we put it. Also, remember on the classic ring when Dr. Carpentier bends it that way, that is the only place he can bend it because that is where the break is in the ring. So it is the only part that is practical.

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Circulation 2006;114;I-588-I-593

DOI: 10.1161/CIRCULATIONAHA.105.001347

Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 72514

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Mitral Valve Repair With Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring for Ischemic Mitral Regurgitation

Early Echocardiographic Results From a Multi-Center Study

Masao Daimon, MD; Shota Fukuda, MD; David H. Adams, MD; Patrick M. McCarthy, MD; A. Marc Gillinov, MD; Alain Carpentier, MD; Farzan Filsoofi, MD; Vivian M. Abascal, MD; Vera H. Rigolin, MD; Sacha Salzberg, MD; Anna Huskin, RN; Michelle Langenfeld, RN; Takahiro Shiota, MD

Background—Ischemic mitral regurgitation (IMR) is associated with asymmetric changes in annular and ventricular geometry. Surgical repair with standard symmetric annuloplasty rings results in a high incidence of residual or recurrent mitral regurgitation (MR). The Carpentier-McCarthy-Adams (CMA) IMR ETlogix annuloplasty ring is the first remodeling ring specifically designed to treat asymmetric leaflet tethering and annular dilatation. We used quantitative 2-dimensional echo to examine early results of mitral valve (MV) repair with the CMA IMR ETlogix annuloplasty ring in patients with IMR.

Methods and Results—Fifty-nine patients (aged 68 ± 12 years) with grade $\geq 2+$ IMR (graded on a scale of 0 to 4+) underwent MV repair with the CMA IMR ETlogix annuloplasty ring. We assessed the mitral annular diameter (MAD), tethering area (TA), and tenting height (TH) of the MV in 4-chamber, 2-chamber, and long axis views at mid-systole before and 3 to 10 days after surgery. After surgery, 57 of 59 (97%) patients had grade 0 or 1+ MR, whereas 2 patients had 2+ MR. MV repair with the CMA IMR ETlogix ring significantly reduced MAD, TA, and TH ($P < 0.001$, for all 3 echo views), particularly in the long axis and 4-chamber views.

Conclusion—Surgical repair of IMR with the novel asymmetric CMA IMR ETlogix annuloplasty ring provided excellent early results with effective reduction of MR, MAD, and leaflet tethering. This novel etiology-specific strategy may result in improved outcomes in IMR patients. (*Circulation*. 2006;114[suppl I]:I-588–I-593.)

Key Words: echocardiography ■ mitral valve ■ myocardial infarction ■ regurgitation

Ischemic mitral regurgitation (IMR) occurs in up to 19% of patients after myocardial infarction (MI)^{1,2} and is an independent predictor of mortality.³ Although some evidence suggests that surgical mitral annuloplasty has a beneficial effect on prognosis in patients with IMR, surgical repair with standard, symmetric, flat annuloplasty rings may leave up to 30% of patients with residual or recurrent mitral regurgitation (MR).^{4–6} The important impact of IMR on survival should challenge surgeons to make every effort to minimize residual MR after mitral annuloplasty. Therefore, new surgical strategies are necessary to improve the treatment for IMR.

IMR has a complex pathophysiology that includes alterations in the geometry and function of the left ventricle (LV), subvalvular apparatus, and mitral annulus.^{7–12} The most common mechanism of IMR is restricted leaflet motion, particularly the posterior leaflet during systole (Carpentier's

type IIIb dysfunction¹³). Recently, it was demonstrated that, in IMR, the pattern of mitral valve (MV) deformation from the postero-medial to the antero-lateral commissura was asymmetrical; MV tethering at the medial aspect also plays a crucial role in the genesis of IMR.¹² Based on these observations, a new remodeling annuloplasty Carpentier-McCarthy-Adams IMR ETlogix ring (CMA IMR ETlogix ring; Edwards Lifescience, Irvine, Calif) was recently developed (Figure 1). This new prosthetic ring specifically addresses the asymmetric deformation characteristic of type IIIb ischemic MR.¹³ Compared with conventional symmetric annuloplasty rings, this new design leads to increased leaflet coaptation through substantial and tailored reduction of the antero-posterior dimension in patients with IMR. The asymmetric 3-dimensional (3D) design with reduced middle to medial (P2-P3) curvature and a slight dip at the P2-P3

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Presented at the American Heart Association Scientific Sessions, Dallas, Tex, November 13–16, 2005.

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DOI: 10.1161/CIRCULATIONAHA.105.001347

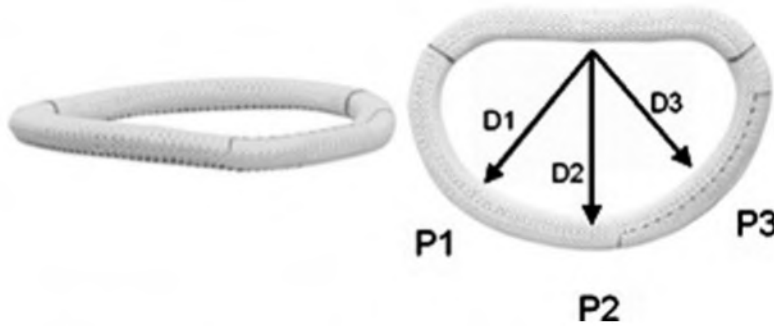


Figure 1. The new asymmetrical Carpentier-McCarthy-Adams IMR Etlogix ring (CMA IMR ETlogix ring). This new ring is undersized with a 14% reduction in the postero-medial dimension (D2, D3 dimension). Note that this ring has a slight dip at P2-P3 (left) and a narrower dimension at P2-P3 (right; D2, D3).

segments increases coaptation of the tethered P2-P3 segments.

In this study, we used quantitative 2-dimensional (2D) echocardiography to assess early operative results of MV repair with the CMA IMA ETlogix ring and to determine its impact on MV geometry in patients with IMR.

Methods

Study Population

We enrolled 59 consecutive patients (age 68 ± 12 years) who underwent MV repair with the CMA ETlogix ring for the treatment of IMR from October 2003 through August 2005 at 3 centers (Mount Sinai Hospital [31 patient], Cleveland Clinic Foundation [13 patients], and Northwestern Memorial Hospital [15 patients]). IMR was defined as significant MR (grade $\geq 2+$ MR assessed by preoperative 2D echocardiography) caused by Carpentier type IIIb or I dysfunction resulting from LV dysfunction caused by coronary artery disease. Patients with other types of mitral dysfunction (type II, excess leaflet motion; type IIIa, restricted leaflet motion in systole and diastole) or patients who had concomitant LV reconstruction were excluded.

All patients had coronary angiography preoperatively and echocardiographic studies before valve repair and 3 to 10 days after surgery (Table 1).

Echocardiographic Measurements

A team from the Cleveland Clinic Foundation (MD, SF with/without TS) traveled to each institution to review all digitalized original echo data for the purpose of consistency of echocardiographic measurements. Preoperative echocardiographic measurements were performed using images recorded 1 to 30 days before surgery (mean, 14 ± 11 days), from transthoracic echocardiography in 49 patients and from transesophageal echocardiography in 10 patients. Transthoracic echocardiography imaging recorded 3 to 10 days after surgery (mean, 5.0 ± 2.2 days) was used for all postoperative measurements. These 2D echocardiographic images were used to assess MV geometry and function, as well as LV dimensions, function, and left atrial dimension. LV end-diastolic volume (EDV) and end-systolic volume (ESV) were measured by the biplane Simpson disk method. Ejection fraction was calculated by the equation $100 \times (\text{EDV} - \text{ESV}) / \text{EDV}$. The characteristics (origin, number, and direction) of MR jets were estimated by color flow Doppler images on a parasternal long and short-axis view at the MV level and on multiple apical views. The severity of MR was graded semi-quantitatively from 0 to 4+ by color Doppler studies of the spatial distribution of the regurgitant jet¹⁴ and the size of the flow convergence/proximal isovelocity surface area from multiple imaging planes.^{14,15} For evaluating geometry of the mitral apparatus, we measured the mitral annular diameter (MAD), tethering area (TA) of the MV (defined as the area enclosed by the annular plane and 2 leaflets), and tenting height (TH) of the MV (defined as the minimal distance between the leaflet coaptation and the mitral annular plane), in 4-chamber (4ch), 2-chamber (2ch), and long-axis (LAX) views at the time of maximal MV closure in systole (Figure 2). The

transmitral velocity, measured by continuous-wave Doppler technique, was used to calculate the trans-mitral mean pressure gradient after mitral valve repair.

Surgical Procedure

Each patient underwent remodeling annuloplasty with the CMA IMR ETlogix ring.¹⁶ Intraoperative transesophageal echocardiography was used to assess LV and MV function during surgical procedure

TABLE 1. Preoperative Patient Characteristics

| Characteristic | No. (%) |
|---|-------------|
| No. of patients | 59 |
| Gender | |
| Male | 40 (67.8) |
| Female | 19 (32.2) |
| Age | |
| Mean | 68 ± 12 |
| Range | 35–90 |
| Previous cardiac procedures | |
| Percutaneous coronary intervention | 15 (25.4) |
| Coronary artery bypass graft | 16 (27.1) |
| N of coronary arteries with stenosis (>50%) | |
| 1 vessel | 14 (23.7) |
| 2 vessels | 13 (22.0) |
| 3 vessels | 32 (54.2) |
| Rhythm | |
| Sinus rhythm | 46 (78.0) |
| Atrial fibrillation | 12 (20.3) |
| Ventricular pacing | 1 (1.7) |
| Risk factor | |
| Hypertension (diastolic pressure >90 mm Hg) | 32 (54.2) |
| Diabetes mellitus | 23 (39.0) |
| Hyperlipidemia (cholesterol >200 mg/dL) | 52 (88.1) |
| Smoking | 18 (30.5) |
| Cerebrovascular accident | 7 (16.9) |
| Renal insufficiency (creatinine ≥ 2.0 mg/dL) | 11 (18.6) |
| Recent myocardial infarction (<14 days) | 7 (11.9) |
| Chronic obstructive pulmonary disease | 8 (13.6) |
| New York Heart Association Class | |
| I | 13 (22.0) |
| II | 23 (39.0) |
| III | 15 (25.4) |
| IV | 8 (13.6) |

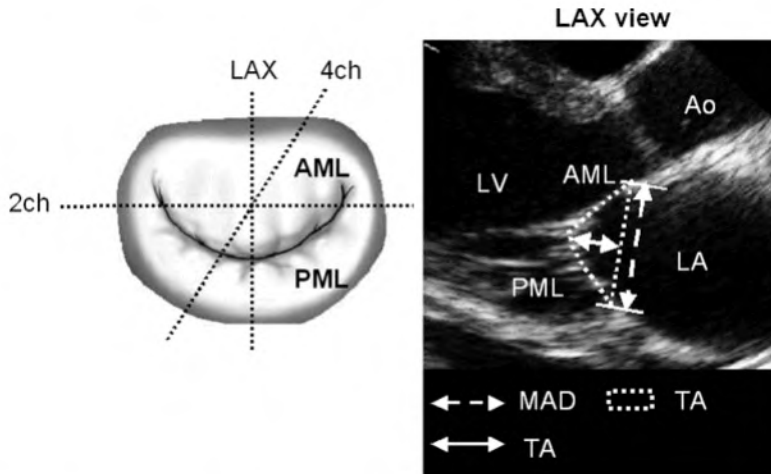


Figure 2. Schematic illustrations of 4-chamber (4ch), 2-chamber (2ch), and long-axis (LAX) views (left), and measurements of mitral annular diameter (MAD), mitral valve tethering area (TA), and mitral valve tethering height (TA) (right). AML indicates anterior mitral leaflet; PML, posterior mitral leaflet.

before and after repair. Coronary artery bypass graft, if required, was performed before MV repair. The mitral valve was approached either through the left atrium or trans-septally. Once interrupted sutures were placed around the annulus, standard Carpentier–Edwards ring sizes were used to size the valve in a typical fashion, taking into account both the anterior leaflet surface area and the inter-commissural distance. A true-sized ring was selected and the remodeling annuloplasty was completed by securing the ring to the annulus with annular sutures;¹⁶ 85% of patients received a ring of labeled size 26 or 28 mm (Table 2). A saline test was performed to confirm a reasonable line of coaptation along the margin of the leaflets.

Statistical Analysis

Data are expressed as mean \pm SD, frequency distribution, or simple percentage. Group comparisons of MAD, TA, and TH of MV in 3 echocardiographic views were performed by repeated-measures analysis of variance (ANOVA) followed by post hoc testing, as appropriate. Sheffe test was used for the post hoc test. The differences in other echocardiographic measurements between preoperative and postoperative values were analyzed by paired *t* test. *P*<0.05 was considered statistically significant.

Statement of Responsibility

The authors had full access to the data and take full responsibility for their integrity. All authors have read and agree to the manuscript as written.

TABLE 2. Mitral Valve Repair Procedure

| | No. (%) |
|---|----------------|
| CMA IMR ETlogix ring size (mm) | |
| Mean | 27.5 \pm 1.6 |
| 26 | 24 (40.7) |
| 28 | 26 (44.1) |
| 30 | 8 (13.6) |
| 32 | 1 (1.7) |
| Concomitant procedure | |
| CABG | 37 (62.7) |
| Ligation of left atrial appendage | 20 (33.9) |
| Maze procedure | 14 (23.7) |
| Tricuspid repair | 15 (25.4) |
| Aortic valve replacement | 7 (11.9) |
| PFO closure | 1 (1.7) |
| Aortic root replacement | 1 (1.7) |
| Transmyocardial laser revascularization | 1 (1.7) |

CABG indicates coronary artery bypass grafting; PFO, patent foramen ovale.

Results

LV and LA chamber and MR Severity

MR grading at baseline and after surgery are shown in Figure 3. At baseline, 13 (22.0%) patients had 2+ MR, 22 (37.3%) patients had 3+ MR, and 24 (40.7%) patients had 4+ MR. The mean MR grade and regurgitant orifice area by proximal isovelocity surface area method were 3.2 \pm 0.8 and 0.39 \pm 0.25 cm², respectively. Intraoperative post-repair echocardiography revealed that all patients had MR that was 1+ or less. Before hospital discharge, 57 patients (97%) had 0 or 1+ MR, whereas 2 patients had 2+ MR. Thus, the mean MR grade was decreased from 3.2 \pm 0.8 to 0.3 \pm 0.6 after surgery. Both patients with 2+ residual MR had infero-posterior LV wall motion abnormalities and 3+ or 4+ MR preoperatively, which was characterized by a single or 2 separate MR jets from the medial and lateral sides. Preoperative 2D echocardiography revealed LV wall motion abnormalities in the antero-septal area in 25 of 59 (42.4%) patients, the infero-posterior area in 41 of 59 (69.5%) patients, and the lateral area in 5 of 59 patients (8.5%). LV end-systolic and end-diastolic volume indices and left atrial size were significantly reduced after surgery (*P*<0.001, for all), whereas LV ejection fraction was unchanged (Figure 4). The transmitral mean pressure gradient after surgery was 3.7 \pm 1.6 mm Hg.

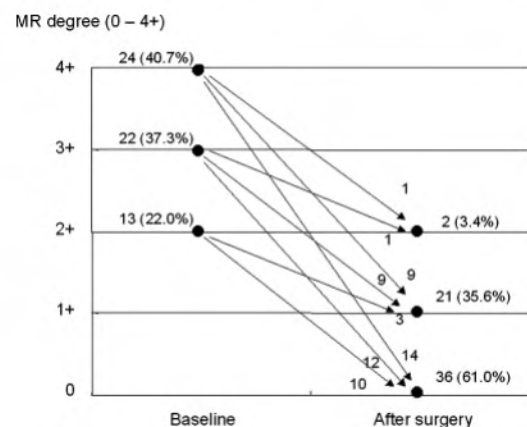


Figure 3. Change in the degree of ischemic mitral regurgitation. After surgery, 57 patients (97%) had 0 or 1+ MR, whereas 2 patients had 2+ MR.

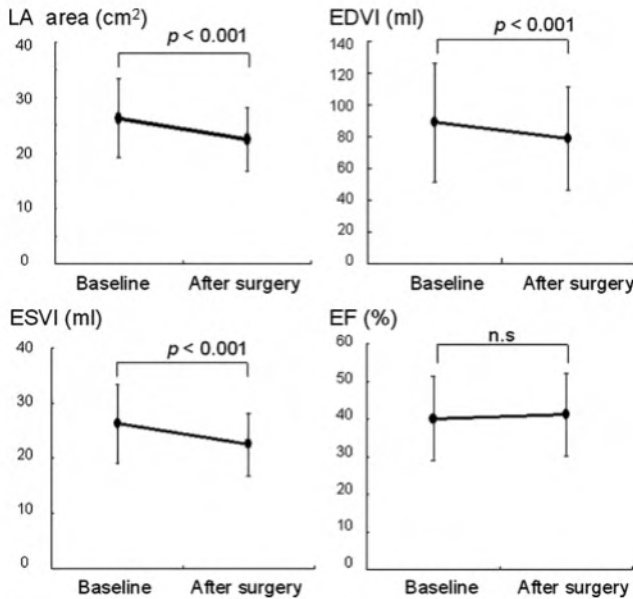


Figure 4. Changes in LV end-systolic and end-diastolic volume indices, left atrial size, and LV ejection fraction after surgery. LV end-systolic and end-diastolic volume indices and left atrial size were significantly reduced after surgery ($P < 0.001$, for all), whereas LV ejection fraction was unchanged. LA indicates left atrial; LVEDVI and LVESVI, left ventricular end-diastolic and end-systolic volume index; EF; ejection fraction.

Mitral Valvular Geometry

Changes in mitral valve geometry assessed by echo at baseline and after surgery are shown in Figure 5. At baseline, measured MAD was similar in 4ch, 2ch, and LAX views (3.0 ± 0.3 , 3.1 ± 0.3 , and 3.0 ± 0.4 cm), indicating circular deformation of the mitral annulus. In contrast, TA and TH of the MV were significantly larger in the LAX view than in 4ch

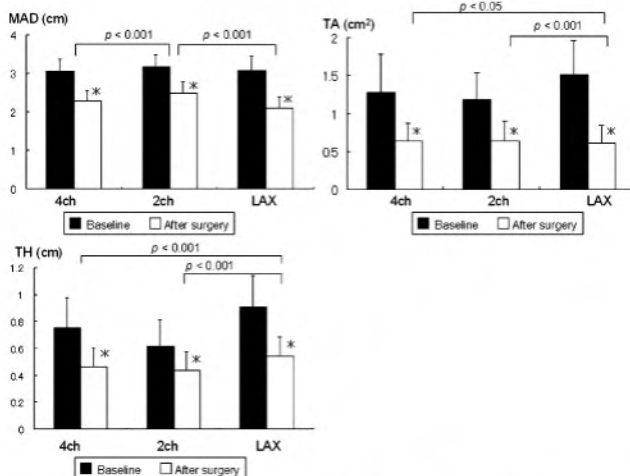


Figure 5. Comparison of MAD, and TA and TH of MV between baseline and after surgery in 4ch, 2ch, and LAX views. The significant reductions of MAD, TA, and TH were observed in all 3 echo views ($*P < 0.001$ for all). The reductions in MAD after surgery were greater in the LAX and 4ch views than in the 2ch one ($P < 0.001$ for both of LAX vs 2ch, and 4ch vs 2ch, respectively). The reductions in TA and TH after surgery were greatest in the LAX as compared with 4ch and 2ch (TA; $P < 0.05$ for LAX vs 4ch, and $P < 0.001$ for LAX vs 2ch, respectively, TH; $P < 0.001$ for both of LAX vs 4ch and LAX vs 2ch, respectively). $*P < 0.001$ vs baseline.

TABLE 3. Early Postoperative Complications

| Complication | No. (%) |
|---------------------------------|-----------|
| Atrial fibrillation (new onset) | 2 (3.4) |
| Arrhythmia | 10 (16.9) |
| Bleeding | 3 (5.1) |
| Pleural effusion | 13 (22.0) |
| Cardiac arrest | 1 (1.7) |
| Congestive failure | 17 (28.8) |
| Pericardial effusion | 1 (1.7) |
| Atelectasis | 1 (1.7) |
| Death | 1 (1.7) |

and 2ch views. Ten patients had TH > 11 mm, which has been suggested as a predictor of residual MR in patients with ischemic or idiopathic cardiomyopathy who have mitral valve annuloplasty.¹⁷ Mitral valve repair with the CMA IMR ETlogix ring significantly reduced MAD, TA, and TH ($P < 0.001$ for all, Figure 5). The reductions in MAD were greater in the LAX and 4ch views than in the 2ch ($P < 0.001$ for both of LAX versus 2ch, and 4ch versus 2ch), reflecting the asymmetric annuloplasty. The reductions in TA and TH were greatest in the LAX views than 4ch and 2ch (TA; $P < 0.05$ for LAX versus 4ch, and $P < 0.001$ for LAX versus 2ch, respectively, TH; $P < 0.001$ for both of LAX versus 4ch and LAX versus 2ch). Among 10 patients with TH > 11 mm,¹⁷ 1 patient had residual 2+ MR after annuloplasty.

Early Morbidity and Mortality

There was one hospital death caused by septic shock after surgery. Complications are presented in Table 3.

Discussion

This study, using quantitative 2D echocardiography, demonstrated that surgical mitral valve repair with the novel, etiology-specific CMA IMR ETlogix ring provided excellent early results with effective annular remodeling leading to a significant reduction in the antero-posterior dimension. These results were achieved by creating asymmetric changes in mitral annular diameter that effectively reduce leaflet tenting and increase leaflet coaptation.

IMR is a growing clinical problem. There is a body of evidence on the negative impact of IMR on medium-term survival in patients with coronary artery disease; the greater the degree of MR, the worse the prognosis, even in patients with mild to moderate MR.³ Recent reports document that 7 800 000 Americans experience MI annually;¹⁸ up to 19% of these patients can be expected to develop MR.^{1,2} Recent studies have suggested that coronary artery bypass graft alone does not completely correct IMR.¹⁹ Therefore, it has been suggested that patients with even mild to moderate IMR should undergo concomitant mitral valve repair at the time of myocardial revascularization.^{6,16} MV repair is now accepted to be superior to replacement in most patients,^{4,20} and undersized ring annuloplasty is commonly used to treat IMR.^{21,22} Nonetheless, MV repair with undersized flexible posterior bands or rings and even symmetric remodeling rings leaves between 10% and 30% of patients with residual or

recurrent IMR.^{4–6} This highlights the need to develop surgical strategies that target the anatomic and pathophysiological changes that contribute to the pathogenesis of IMR.^{7–12}

The initial insult in IMR is LV remodeling after myocardial ischemia or MI, which subsequently leads to posterior-medial and apical displacement of the posterior papillary muscle.^{10,11} Associated regional annular and subvalvular distortion leads ultimately to poor leaflet coaptation. Recent clinical studies have provided precise quantitative and morphological descriptions of IMR. Kwan et al¹² reported that the pattern of MV deformation from the postero-medial to the antero-lateral commissura is asymmetrical in IMR, whereas it is symmetrical in dilated cardiomyopathy. These differences in MV geometry emphasize the fact that in patients with IMR, the P2 and P3 segments are often asymmetrically restricted and associated with asymmetrical annular dilatation. Thus, treating IMR with an undersized symmetrical ring may not be the optimal approach to MV repair in IMR.⁶

With this improved pathophysiological understanding of IMR, a novel remodeling annuloplasty, the CMA IMR ETlogix ring was developed. This new prosthetic ring incorporates the principles of undersizing and specifically addresses the asymmetric deformation observed in type IIIb ischemic MR. Compared with a conventional symmetric annuloplasty, this new design leads to increased leaflet coaptation by a 3D asymmetric reduction in the antero-posterior dimension (Figure 1 right, D2 and D3 dimension) and a dip at P2-P3 segments (Figure 1 left). The new ring downsizes the medial (D3) dimension 2 sizes and the middle (D2) dimension by 1 size when compared with standard annuloplasty rings; thus, by design, this is an undersized annuloplasty. This integral feature makes it possible to select a CMA IMR ETlogix ring based on the anterior leaflet surface area measured with a standard sizer, while achieving precise remodeling with optimal coaptation in the P2-P3 region. Furthermore, this remodeling ring contains a rigid titanium core, providing complete fixation of the septal-lateral dimension during the entire cardiac cycle, which is optimal in patients with IMR.²⁰ These designs provided high early success rates (9/10, 90%) even in “high-risk patients” with TH >11 mm.¹⁷ Long-term follow-up is required to assess the durability of this result.

Study Limitations

The present study used a retrospective analysis of routine clinical echocardiographic data. Geometric changes in the mitral valve apparatus were evaluated using routine 2D echocardiography. More precise assessment by 3D echocardiography was not performed. However, we were able to quantify changes in annular geometry and leaflet coaptation in multiple 2D planes. A low incidence of residual MR after surgery and effective reductions of MAD and MV tethering were observed, indicating that the design of the CMA IMA ETlogix ring was suitable for annuloplasty in patients with IMR. Further investigations including 3D echocardiographic examination is needed to amplify understanding of geometric changes in the mitral apparatus with this technique.

We estimated MR severity semi-quantitatively by color Doppler techniques for comparison and did not quantify the

severity of IMR after surgery. However, it was relatively easy to detect significant reductions in the color jet or flow convergence to confirm the efficacy of annuloplasty. In addition, significant residual MR was not observed; therefore, quantitative methods were not necessary to assess residual MR after surgery.

Finally, this study was conducted to examine early geometric changes and operative results after annuloplasty with the CMA IMR ETlogix ring in a small number of patients. Further investigation is needed to confirm long-term effectiveness of this procedure in larger populations.

Conclusion

The present study showed that surgical repair of IMR with the novel asymmetric CMA IMR ETlogix ring provides excellent early results with geometric changes that include reductions in MAD and leaflet tethering. This novel, etiology-specific strategy may result in improved outcomes in IMR patients, including a lower incidence of residual or recurrent MR.

Source of Funding

This study was supported by research grant from Edwards Lifesciences, LLC.

Disclosures

Drs Adams, Carpentier, Gillinov, and McCarthy, have served as consultants to Edwards Lifesciences, LLC. Drs Carpentier, McCarthy and Adams are inventors and receive royalties from Edwards Lifesciences, LLC.

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From: Wilkie, Robert L., Jr.
Sent: Thu, 19 Mar 2020 21:57:04 +0000
To: RLW
Subject: FW: [MARKETING] [EXTERNAL] Coronavirus News: Spending Packages, Elective Surgeries and More

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Sent: Thursday, March 19, 2020 5:32:41 PM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [MARKETING] [EXTERNAL] Coronavirus News: Spending Packages, Elective Surgeries and More

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March 19, 2020 | www.aha.org/news

Coronavirus Update: News on Congressional Packages, Elective Surgeries, PPE Conservation and Cyber Resources

Congress urged to allocate \$100 billion to providers in next COVID-19 spending package. The AHA, American Medical Association and American Nurses Association today urged congressional leaders to provide \$100 billion to front line health care personnel and providers and "direct the federal agencies to begin to infuse funds immediately so that they can afford to take the necessary steps to fight" the novel coronavirus outbreak (COVID-19). **See the [letter for more details](#) about the specific requests.**

Last night, President Trump signed legislation that, among other areas, eliminates patient cost-sharing for COVID-19 testing and related services; establishes an emergency paid leave program; expands unemployment and nutrition assistance; provides a temporary increase in the Medicaid Federal Medical Assistance Percentage (FMAP); and creates two mechanisms for coverage of testing for the uninsured — one through the Medicaid program and another through the Public Health and Social Services Emergency Fund.



CORONAVIRUS UPDATE

AHA, others recommend action to strengthen provider capacity, resources. The AHA and 17 other organizations representing health care providers, insurers, suppliers and others yesterday urged Congress to take certain immediate actions to strengthen health care capacity and ensure a stable supply of critical resources to address the novel coronavirus.

"To meet unprecedented demand, the most critical supplies needed are equipment for testing, personal protection of care providers, and respiratory support for patient care," the groups wrote. "We recognize that the President has invoked the Defense Production Act and urge the federal government to expeditiously move to spur massive, increased production, distribution, and access to gowns, masks, gloves, testing kits, testing swabs, and respiratory machines."

The organizations also urge specific actions to strengthen provider capacity and drive patients to appropriate alternative care sites, and to ensure continued access to critical medications and avoid supply-chain disruptions.

CMS issues guidance for elective surgery; PPE conservation strategies. The Centers for Medicare & Medicaid Services yesterday issued guidance to help hospitals and health systems evaluate whether to provide elective surgeries during community spread of COVID-19. The agency proposes a tiered framework based on the urgency of the procedure, health of the patient and surgical setting that facilities can use to determine whether to perform or postpone surgery.

In a statement AHA said, "America's hospitals and health systems are intensely focused on the challenge of dealing with COVID-19 as they continue to provide medical care for patients and work to protect their communities. We simply could not manage this crisis without the hard-working and dedicated physicians, nurses and other front line staff who care for patients and maintain our facilities and equipment.

"As we make additional preparations, it's important to recognize that the cancellation of elective procedures — which the medical community needs to be prepared to implement — should be determined at the local, community level in consultation with hospitals and the clinical recommendations of physicians and nurses. It is important to recognize the definition of 'elective' procedures includes important life saving measures that will continue to be necessary. In issuing this framework, CMS took an appropriate step that provides a balanced approach to address this matter."

The Centers for Disease Control and Prevention also has proposed strategies for optimizing personal protective equipment supplies, including eye protection, isolation gowns, facemasks and N95 respirators.

AONL CEO attends White House meeting on COVID-19. Robyn Begley, CEO of AHA's American Organization for Nursing Leadership, yesterday attended a White House meeting with President Trump, Vice President Pence, members of the Coronavirus Task Force and leadership from national nursing organizations to discuss nursing's response to the COVID-19 pandemic.

"The top priorities for nurse leaders are to ensure nurses have the supplies and equipment they need to treat patients, allocate nurses so we have enough staff to safely care for our patients and communities, and keep our nurses and their families safe," Begley said, stressing the critical need to increase the production of N95 respirators and ventilators.

She also advocated for removing licensing barriers; using creative strategies to maximize the workforce, such as roles for recently retired nurses and furloughed school nurses; and underscored the importance of caring for nurses and their families during this unprecedented time.

"It is important they know we are committed to their safety," she said. "We depend on nurses coming to work while their families, including children and elders, are at home. Child and elder care are essential."

New COVID-19 cyber resources available. The AHA has released a compendium of resources for hospitals and health systems related to cybersecurity threats during the COVID-19 pandemic. In addition, John Riggi, AHA's senior advisor for cyber and risk, today published a blog offering four ways that health care providers and organizations can mitigate cyber risks during the pandemic.

Moody's: Hospital financial outlook negative as coronavirus constrains cash flow. Moody's Investors Service today revised its outlook for the U.S. nonprofit hospital and health care sector from stable to negative, saying revenue will likely decline as hospitals cancel elective surgeries and other services to prepare for a surge of coronavirus cases. "At the same time, expenses will rise with higher staffing costs and the need for supplies such as personal protective equipment," the credit rating agency said. "...Ripple and lingering effects to the economy will also drive lower cash flow even after the outbreak is contained. These include a reduction in the value of hospitals' investment portfolios and potential rising unemployment or widespread layoffs that result in the loss of health benefits. The difficulties facing hospitals come amid increasing cash flow constraints, such as a greater reliance on reimbursement from governmental programs and a continued shift in treatment to less costly settings."

USP issues compounding guidance. U.S. Pharmacopeia yesterday issued guidance on strategies for conserving sterile compounding personal protective equipment and for compounding alcohol-based hand sanitizers to address consumer shortages during the COVID-19 pandemic. The Food and Drug Administration recently said it does not intend to take action against compounders that prepare alcohol-based hand sanitizers for consumer use for the duration of the COVID-19 emergency, provided that certain production guidelines are met.

CMS issues new FAQs on Medicaid/CHIP, catastrophic health plan coverage. CMS yesterday updated its FAQ for state Medicaid and Children's Health Insurance Program agencies, answering questions related to flexibilities related to managed care, benefits, financing, Section 1115 demonstrations, and Section 1135 waivers offered as part of the

president's declaration of a national emergency.

The agency also clarified coverage of COVID-19 diagnosis and treatment by catastrophic health plans. The document aligns with guidance released last week by the Internal Revenue Service, which gave high deductible health plans flexibility to provide COVID-19 diagnosis and treatment benefits without deductibles or cost-sharing.

KFF tool provides state-level data on COVID-19 cases. The Kaiser Family Foundation has released a new, regularly updated tool for tracking coronavirus policy actions, along with data on current cases and deaths, and state-level data on health coverage and provider capacity.

Hospitals can apply for free medical devices to assist with COVID-19 response. Hillrom will donate \$3 million in medical devices for critical and intensive care environments to 25 U.S. hospitals fighting COVID-19, the company announced today. The medical technology company will provide 25 ICU technology packages at no cost to hospitals that meet certain criteria, including demonstrated need. The donations include intensive care unit beds and patient monitoring and respiratory health devices. For more information and to apply, click here. "The women and men of America's hospitals and health systems are on the front lines every day, treating and helping prevent the spread of COVID-19," said AHA President and CEO Rick Pollack. "We appreciate Hillrom's important donations to help hospitals, health systems and health care providers expand access to critical care technologies as they respond to the novel coronavirus pandemic."

COVID-19 Events & Educational Opportunities

Register now: March 23 CDC COVID-19 webinar for rural partners

.....
The Centers for Disease Control and Prevention March 23 at 1 p.m. ET will host a webinar for rural partners with Jay Butler, M.D., deputy director for infectious diseases, who will share guidance with partners, public health practitioners, health care providers and others working to protect the health of rural communities. You can submit questions in advance to eocevent337@cdc.gov indicating that questions are for the 3/23 call. Questions not answered during the call may be sent to ruralhealth@cdc.gov. **View more information and register here.**

Webinar replay: Caring for patients with serious illness during COVID-19

.....
The Center to Advance Palliative Care, an AHA partner, has released a recording of its March 18 webinar on caring for patients with serious illness, who are at higher risk for COVID-19. **Replay the webinar here.**



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800 10th Street, NW, Suite 400, Washington, DC 20001

From: (b)(6)
Sent: Thu, 19 Mar 2020 23:39:59 +0000
To: RLW
Subject: [EXTERNAL] Fwd: Medical staff describe shortages and rationing of masks as White House assures they're available 'now'

(b)(6)

Begin forwarded message:

From: POLITICO Pro <politicoemail@politicopro.com>
Date: March 19, 2020 at 7:29:25 PM EDT
To: (b)(6)@riponsociety.org
Subject: **Medical staff describe shortages and rationing of masks as White House assures they're available 'now'**
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-775930271-1376319-328039@politicoemail.com>

Medical staff describe shortages and rationing of masks as White House assures they're available 'now'

By Alice Miranda Ollstein

03/19/2020 07:25 PM EDT

Doctors and nurses across the U.S. say shortages of masks and other safety gear are putting them and their coworkers at risk, despite White House assurances that the supply gaps from the coronavirus pandemic are being addressed by policy fixes and donations from good Samaritans.

As health providers take to social media to plead with the federal government to make more gear available, and state officials hold press conferences begging other industries to donate masks to their local hospitals, President Donald Trump and Vice President Mike Pence insisted from the White House podium Thursday that plenty of masks are available now.

“We put a priority at the president's direction on making sure health care services through America have the protection to keep themselves and their family safe,” Pence said, saying that the bill Congress approved this week lifting legal liability for masks not previously approved for hospital use will allow tens of millions produced by the company 3M and others to be sold for the treatment of coronavirus patients.

“We vastly increased the supply of medical masks and we'll continue to put a priority on making sure we are calling on industry at every level, calling on major suppliers that the president met

with this week to make sure those equipment are there,” he said.

Guidance from the CDC released Monday that bluntly acknowledged the shortages tells another story. That advice, which health care workers tell POLITICO they consider dangerous, includes reusing respirator masks between different patient visits, using masks that have passed their expiration date, and even constructing “homemade” masks out of a bandana or scarf.

With medical workers already getting sick and dying from the disease in Washington state and other coronavirus hot spots, health care workers tell POLITICO they’re terrified for themselves and their patients.

“It’s the scariest thing about going to work every day,” said Sean Petty, a pediatric ER nurse and member of the New York State Nurses Association. Petty told POLITICO that his public sector hospital in the Bronx implemented what he described as “extreme rationing” of masks this week.

Petty also noted the shortage has forced his hospital to only provide masks to patients who have severe enough symptoms to qualify to be tested for coronavirus — which could be risky because the transmission of the virus from asymptomatic patients is not fully understood.

Despite the ramped-up domestic production the Trump administration touted Thursday, those on the ground say it’s unclear when those supplies will make it into medical providers’ hands.

The 500 million masks the federal government ordered this week, for example, may not be delivered for another 18 months.

Jamie Lucas, executive director of the Wisconsin Federation of Nurses and Health Professionals, said Thursday that none of his members have heard from their employers that more masks are on the way.

“They’re preparing as if what they have is what they’ll have,” he said, including rationing and reusing masks in potentially unsafe ways.

A 2006 report by the National Academies of Sciences’ Institute of medicine both predicted the current shortage and warned against the repeated use of a single mask.

“These devices will be in short supply if a pandemic strikes,” the report found. “And there is currently no simple, reliable way to decontaminate these devices that would enable people to safely use them more than once.”

A registered nurse at a large nonprofit hospital in Manhattan, who spoke on condition of anonymity for fear of losing her job, told POLITICO she was given an online training last week about the protective gear she needed to wear when caring for potential coronavirus patients and that the training stressed the use of an n-95 respirator mask.

But when she was called in this week to assist with a patient showing flu-like symptoms, she was told by management that a regular surgical mask was adequate protection — echoing the recent shift in the CDC’s guidelines. Despite deep misgivings, she spent hours in the room with the

patient.

“I’m worried about myself and my colleagues being put at risk, and I’m also worried that we’re not doing nearly enough to prevent transmission from infected patient to staff to other patients who may be immunocompromised,” she said.

Nurses and doctors are not the only ones at risk.

Lucas told POLITICO that hospital cleaning staff have been directed to clean rooms that held coronavirus patients without a mask in order to conserve them for medical providers. Even with new data showing the virus can survive on surfaces for hours, the unprotected cleaners are expected to turn over the rooms for new patients much more quickly.

As of Thursday afternoon, hundreds of thousands of health care workers had signed an online petition demanding the government do more to ensure an adequate supply of masks and other protective equipment.

Yet federal aid has been slow to arrive.

On Wednesday, the Trump administration invoked the Defense Production Act to ramp up production of desperately needed hospital equipment. Though the White House had discussed taking this step for weeks, it has not yet done the required assessment of what supplies are most in need, meaning those items may take months to actually make it to the front lines. Trump also indicated he was in no hurry to move forward, tweeting this week that he only signed the act “should we need to invoke it in a worst case scenario in the future.”

Many states say that “worst case scenario” has arrived.

On Thursday, Massachusetts lawmakers wrote to the Trump administration saying they had only received 10 percent of the 750,000 masks and other equipment they requested weeks ago, and warned that the state's hospitals are "facing or are imminently anticipating shortages."

The office of Washington Gov. Jay Inslee, whose state has more than 900 confirmed cases, said Thursday there are still "substantial shortages" of protective gear despite two shipments from the Strategic National Stockpile. Inslee's office said the federal government hasn't filled the state's most recent request for tens of thousands of additional N-95 respirators, surgical masks and face shields.

The stockpile of medical equipment, originally designed for use during a nuclear disaster or biological attack, was never intended to last during a prolonged pandemic.

Officials in Ohio say what they’ve received from the stockpile falls far short of hospitals' needs.

“Ohio has received our full allocation from the national strategic stockpile,” Tamara McBride, the chief of the Bureau of Health Preparedness at the Ohio Department of Health, told reporters earlier this week. “If we do not take conservation steps now, we will not have health care workers that are protected to care for the most sick.”

Like other states, Ohio's leaders have asked veterinarians and dentists to donate masks and other materials to hospitals. They have also asked food service workers to donate latex gloves. A hospital in Atlanta has even had to rely on a donation of masks, gloves, and gowns from a TV medical drama being filmed nearby.

Pence lavished praise Thursday on the construction industry for responding to the federal government's call to donate masks, but did not say how many have been obtained that way. And as recently as Tuesday, the Association of General Contractors said the administration had not consulted with it about this request, and the group worried that the loss of masks would put their own workers at risk.

"Without those masks, they would be immediately out of work, because they can't work without masks," said Vice President of Public Affairs Brian Turmail.

AGC added Thursday that HHS had asked the group to send an inventory of all their members' available safety equipment, including masks and protective suits, but no donations have yet been made. "We are going to ask our chapters tomorrow morning to collect this information and share it with HHS," Turmail said.

In the meantime, all sectors of the medical community are doing whatever they can to conserve masks. Medical students, for example, have halted their clinical rotations, and hospitals have suspended elective procedures.

Janis Orłowski, chief health care officer at the Association of American Medical Colleges, told reporters on a call Thursday that the lack of masks and other personal protective equipment remains the "number one issue" she's hearing from teaching hospitals battling coronavirus.

"Are we worried about this? Yes, we are," she said. "We are really going to have to push to get more PPE into the hands of our health care workers."

Gavin Bade contributed reporting.

To view online:

<https://subscriber.politicopro.com/trade/article/2020/03/medical-staff-describe-shortages-and-rationing-of-masks-as-white-house-assures-theyre-available-now-1897985>

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Sent: Fri, 20 Mar 2020 11:57:39 +0000
To: RLW
Subject: [EXTERNAL] Fwd: Lobbyists make a mad dash to shape coronavirus stimulus package

(b)(6)

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From: POLITICO Pro <politicoemail@politicopro.com>
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To: (b)(6)@riponsociety.org
Subject: Lobbyists make a mad dash to shape coronavirus stimulus package
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-775930271-1376319-328984@politicoemail.com>

Lobbyists make a mad dash to shape coronavirus stimulus package

By Theodoric Meyer

03/20/2020 07:22 AM EDT

Senate Republicans raced this week to introduce a trillion dollar coronavirus stimulus package. Lobbyists for industries left reeling by the pandemic were hustling just as hard to shape it.

The bill's unveiling on Thursday capped an extraordinary week on K Street in which trade group after trade group asked Congress for sums that would have been unfathomable just a few weeks ago: \$1.4 trillion to shore up the manufacturing sector, \$4 billion for museums, \$100 billion for doctors, nurses and hospitals.

The Senate's breakneck work to craft relief legislation this week has driven a frantic effort from industries crippled by measures taken to slow the spread of the virus as well those who have suffered less harm.

Not everyone got what they wanted in Senate Majority Leader Mitch McConnell's bill. But it wasn't for lack of trying.

"The Hill appears to be overwhelmed with people advocating for why they're uniquely affected by the coronavirus epidemic," said Sean Kennedy, the top lobbyist for the National Restaurant Association, which asked Congress for more than \$300 million in relief this week.

The restaurant association has mobilized its members to make tens of thousands of phone calls to their lawmakers. With many restaurants shuttered to slow the virus' spread, their proprietors have had plenty of free time to become armchair lobbyists, Kennedy said.

Other lobbyists have pleaded their clients' cases to a handful of aides to top Republican senators, such as Erica Soares in McConnell's office and Nick Rossi, who's chief of staff to Sen. John Thune (R-S.D.), the No. 2 Senate Republican.

Some lobbyists for industries hit hard by the restrictions imposed by coronavirus were underwhelmed by what they got in McConnell's bill: \$58 billion in loans and loan guarantees for the airlines and another \$150 billion for other "severely distressed sectors" of the economy, as well as nearly \$300 billion in loans for small businesses.

"We think it will be insufficient to stem the tide of job loss and closing of hotels that we're seeing, candidly," said Brian Crawford, the top lobbyist for the American Hotel & Lodging Association. "We're hoping this is an opening salvo."

"It needs to be bigger," said Tori Barnes, the top lobbyist for the U.S. Travel Association, even though she praised of the measures it includes.

The hotel and travel industries personally pleaded their cases to President Donald Trump and Vice President Mike Pence in a meeting at the White House on Tuesday, warning that the industry could shed millions of jobs in the coming weeks without significant help. The hotels asked for \$150 billion in grants, along another \$100 billion for the broader travel industry.

McConnell's bill would force hotels and the travel industry to compete with restaurants, casinos, distillers, moving companies and manufacturers — all of which have asked for aid this week — for \$150 billion in loans.

The legislation will need the support of Senate Democrats to pass, giving lobbyists for industries that feel they've gotten short shrift another chance to shape the bill before senators leave town in the coming days.

Not every industry lost out in McConnell's bill. The airlines, which asked for \$59 billion in cash, loans and loan guarantees, got \$58 billion in loans. Nick Calio, the head of Airlines for America, the industry's trade group, said the money will keep the airlines going for five to six more months.

"We have been hit the hardest of anyone by this," he said in an interview.

The National Retail Federation, meanwhile, secured a tweak to the Republican tax law that it had been pressing for since shortly after its passage in 2017. The fix would return an estimated \$15 to \$30 billion to hotels, restaurants and retailers that have upgraded their properties over the past two years but haven't gotten a tax break for it, according to the trade group.

David French, the National Retail Federation's top lobbyist, said it was harder to lobby for the provision because he couldn't meet with senators or their staffers in person, with the Hill mostly

closed to visitors.

“It’s working, but it’s certainly not like in the old days,” he said.

Lobbyists’ inability to meet with lawmakers and administration officials face to face hasn’t stopped them from trying to cash in on their connections.

“Have you adjusted your consultant strategy and team lineup in light of the new Corona virus realities?” the lobbyist Terry Allen wrote in an email to potential clients on Thursday morning. “Fidelis Government Relations now has best in class reach into both VP Mike Pence and incoming White House Chief of Staff Mark Meadows.”

The lobbying shop boasts the services of Pence’s former chief of staff, Bill Smith, as well as Wayne King, a former aide to Rep. Mark Meadows (R-N.C.), whom Trump tapped earlier this month to become his next White House chief of staff, Allen wrote in the email, which was obtained by POLITICO. Pence is “quarterbacking the government’s response to the Corona virus,” he added.

In an interview, Allen said he’d already gotten a call from a potential client in response to the email. While the pitch emphasized the government’s coronavirus response, Allen said the pandemic wasn’t the focus of the firm’s lobbying efforts.

“Regardless of whether the coronavirus is prominent, our lineup is strong,” he said.

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<https://subscriber.politicopro.com/financial-services/article/2020/03/lobbyists-make-a-mad-dash-to-shape-coronavirus-stimulus-package-1898564>

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From: Wilkie, Robert L., Jr.
Sent: Fri, 20 Mar 2020 19:23:24 +0000
To: RLW
Subject: FW: [MARKETING] [EXTERNAL] Thank you!

From: Hero Industries
Sent: Friday, March 20, 2020 3:22:22 PM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [MARKETING] [EXTERNAL] Thank you!

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From: Wilkie, Robert L., Jr.
Sent: Fri, 20 Mar 2020 22:57:24 +0000
To: RLW
Subject: FW: RE RFI Corona Virus quarantined traveler housing?

From: (b)(6)
Sent: Friday, March 20, 2020 6:56:25 PM (UTC-05:00) Eastern Time (US & Canada)
To: (b)(6)
Cc: (b)(6)
(b)(6) MD; (b)(6); WILKIE, Robert L., Jr.; Stone, Richard A., MD
Subject: [EXTERNAL] Re: RE RFI Corona Virus quarantined traveler housing?

Hi (b)(6)

Please see below, to date I still have not recieved a response to any of the questions below. It would be nice to get an actual response from someone in VHA before we have an RN who gets critically ill. We already have several RNs sick with sytoms awaiting test results and another currently in the hospital.

Secretary Wilkie/Dr. Stone: I know this Administration is Anti Union and wants to ignore the Unions, but this is about the health and safety of the Veterans and RNs who care for them, its time to engage the RNs on the frontlines.

(b)(6)

From: (b)(6)@nationalnursesunited.org>
Sent: Tuesday, March 10, 2020 10:25 AM
To: (b)(6)@va.gov>
Cc: (b)(6)@gmail.com>; (b)(6)
<(b)(6)@nationalnursesunited.org>; (b)(6)@va.gov>; (b)(6)
(b)(6)@va.gov>; (b)(6)@va.gov>; (b)(6)@va.gov
<(b)(6)@va.gov>

Subject: Re: RE RFI Corona Virus quarantined traveler housing?

Hi (b)(6)

I figured since we may have limited time on the briefing on Wednesday, I wanted to provide you questions ahead of time.

If you could please provide responses to each of these questions asap it would be appreciated.

1. What is VA plan for facilities that have insufficient amounts of PPE (N95/PAPR) currently to ensure the safety of RNs, healthcare workers, veterans and the prevention of the spread of COVID 19?
2. What is the VA plan if there is not enough staff to take care of patients due to exposure causing staff to quarantine?
3. Is VA going to be testing RNs and employees for COVID 19? If so, when?
4. What is the plan in each facility to notify the staff when there is either confirmed COVID 19 or suspected case?

5. What is plan/protocol/questions for screening patients, staff, visitors upon entry to the hospital. If they answer yes to any question that they might be symptomatic for COVID 19, what is the protocol then?
6. What is the VA policy on quarantining of employees who have traveled to China, South Korea, Iran or Italy recently?
7. What is the VA policy for those employees who have interacted with other employees who now being quaranted due to interaction with those who have tested positive for COVID 19?
8. Do the medical centers now have full authority to grant weather and safety leave for up to 15 days for anyone needing to be quarantined? If so, please define who you believe is subject to quarantine?

Thanks,

(b)(6)

From: (b)(6)@va.gov>

Sent: Monday, March 9, 2020 8:49 AM

To: (b)(6)@nationalnursesunited.org>

Cc: (b)(6)@gmail.com>; (b)(6)
(b)(6)@nationalnursesunited.org>; (b)(6)@va.gov> (b)(6)
(b)(6)@va.gov>; (b)(6)@va.gov>

Subject: RE: RE RFI Corona Virus quarantined traveler housing?

Good morning (b)(6)

I sincerely apologize. The Dr. who will be giving the brief is deployed on the team to manage COVID-19. I have not received date(s) of his availability for a briefing to date. I followed up with his EA again this morning and will get back to you as soon as I hear something.

From: (b)(6)@nationalnursesunited.org>

Sent: Friday, March 6, 2020 8:47 PM

To: (b)(6)@va.gov>

Cc: (b)(6)@gmail.com>; (b)(6)
(b)(6)@nationalnursesunited.org> (b)(6)@va.gov>

Subject: [EXTERNAL] Re: RE RFI Corona Virus quarantined traveler housing?

(b)(6)

We are starting to hear about change in protocols related to screenings of staff, patients, and visitors, Telework being used, usage of leave and other issues.

To that end, when will NNOC.NNU be briefed on COVID 19?

(b)(6)

From: (b)(6)@va.gov>
Sent: Thursday, March 5, 2020 11:39 AM
To: (b)(6)@nationalnursesunited.org>
Cc: (b)(6)@gmail.com>
Subject: RE RFI Corona Virus quarantined traveler housing?

Good morning (b)(6)

Just FYSA, I was assigned this RFI today. I will reach out to the responsible program office to obtain the information. Also, just an update, as of 1138 EST 3-5-20, I am still waiting on date/time from the SME regarding the informational briefing on the Corona Virus.

r/ (b)(6)

From: (b)(6) (6)@nationalnursesunited.org>
Sent: Monday, February 3, 2020 11:26 AM
To: (b)(6)@nationalnursesunited.org>; (b)(6)
<(b)(6)@va.gov>
Cc: (b)(6)@nationalnursesunited.org>; (b)(6)@comcast.net>;
(b)(6)@va.gov>; (b)(6) CIV USN (USA)
(b)(6) (6)@navy.mil>; (b)(6)@va.gov>
Subject: [EXTERNAL] Re: Corona Virus quarantined traveler housing?

Hi (b)(6)

I wanted to follow up on the email below as we have recently seen an All Employee Message from Dr. Stone today, but there was no mention of VA facilities being used to house travelers who are being quarantined.

Please provide us an update asap, as well as the information requested below.

Thanks,

(b)(6)

From: (b)(6)@nationalnursesunited.org>
Sent: Sunday, February 2, 2020 2:28 PM
To: (b)(6)@va.gov>
Cc: (b)(6)@nationalnursesunited.org>; (b)(6)
(b)(6)@nationalnursesunited.org>; (b)(6)@comcast.net>; (b)(6)
(b)(6)@va.gov>
Subject: Corona Virus quarantined traveler housing?

It is my understanding that the Department of Veterans Affairs is entertaining housing travelers who are currently under quarantine due to exposure to the Corona virus. We are deeply concerned that moving these travelers to VA medical facilities poses a grave danger to nurses, staff, veterans, as well as the general population.

It is our understanding that the medical staff has not been trained on dealing with patients who may be infected with this virus. We are also deeply concerned the VA has not trained staff on the use of appropriate personal protective equipment (PPE). Additionally, there is a question as to whether the VA has the appropriate PPE. We have sent the below information request to each of the 23 facilities we represent and are awaiting response. Given the concerns raised above I am escalating this request to your office for immediate response.

Information requested:

1. Facilities that are designated as quarantine housing sites for travelers who have entered the U.S. from China. As well as start date, duration .
2. The Facility plan for disaster preparedness and response in the case of mass influx of patients or mass casualty incident;
2. The Facility Infection Control Guidelines, Policies, and other related documents regarding treatment, surveillance, and isolation precautions for patients with known or suspected Novel Coronavirus;
3. The Facility plan for exposure surveillance, prompt notification, and isolation (if indicated) of employees with occupational exposure to Novel Coronavirus;
4. The Facility Infection Control Guidelines, Policies, and other related documents regarding employees working while exhibiting signs and/or symptoms of Novel Coronavirus and/or any potentially communicable disease;
5. Any and all training and education materials, whether written, delivered via electronic means, or provided by in-person instructor(s) regarding Novel Coronavirus, including screening for symptoms and travel history that may indicate the need for further screening and/or isolation, as well as general information about Novel Coronavirus infection and treatment;
6. The number of available airborne isolation (negative pressure) rooms in the Facility;

7. Current stock on hand of N95 respirators and powered air-purifying respirators (PAPRS) as well as gowns, gloves, and other PPE for droplet and aerosol precautions;
8. Please provide a list of areas that could be used to isolate a patient with suspected or possible 2019-nCoV infections if an airborne isolation room is not available;
9. The Facility procedure(s) used to determine daily whether negative pressure is maintained with the airborne isolation room is in use;
10. Has the Facility identified any possible cases of 2019-nCoV? If so, how many?
11. The Facility's plans to adjust staffing to address the additional staff time required to properly care for multiple patients in airborne isolation; and
12. The Facility Attendance Policy and any revisions to the Attendance Policy made in order to address employees with documented exposure or known/suspected Novel Coronavirus.

We understand that this is a developing situation. To the extent that educational materials, supply levels, and policies may be in flux, please consider this information request to be ongoing and provide additional materials as they become available.

Particularized need:

1. Determine if the Hospital is complying with the Collective Bargaining Agreement, as well as all other applicable laws, rules, and regulations;
2. Determine if all RNs are being effectively protected from infectious disease exposure;
3. Determine the most appropriate representational course of action to take in this matter;
4. Fulfill the Union's representation responsibilities;
The Union will use this information to assess the Facility's preparedness for the current Novel Coronavirus outbreak and its impact upon RNs employed at the Facility.

If any part of this request is denied, or if any material is unavailable, please communicate that fact to me in writing, along with the reason(s) for the denial or unavailability of the requested information, and please provide the remaining items by

the same date. The Union will accept partial fulfillment of this information request without prejudice to its position that we are entitled to all documents and information called for in the request.

The Union reserves the right to request additional information if necessary. To the extent that any of the above information can be provided in electronic format, please do so.

From: Wilkie, Robert L., Jr.
Sent: Fri, 20 Mar 2020 23:06:46 +0000
To: RLW
Subject: FW: VA violates federal laws
Attachments: APPLICATION.pdf

From: Sandra Thornton
Sent: Friday, March 20, 2020 7:05:22 PM (UTC-05:00) Eastern Time (US & Canada)
To: The White House; Eric Trump; Donald J. Trump; Sandra Thornton; Donald J. Trump; Team Trump Florida; Senator Marco Rubio; Congressman Gus Bilirakis
Cc: VAVBAWAS/CO/Office of the USB VBA; VAVBAWAS/AMO/DIR; VAVBAWAS/AMO/COMMS; VA Accountability Team; Clark, Willie, VBAVACO; Michael.Pence@mail.house.gov; Wilkie, Robert L., Jr.; Bevins, Debi; Kristen.Sellars@mail.house.gov; VHA Client Services Response Team; Hannity@foxnews.com; pkime@militarytimes.com; Rasmussen, Deena L., VBAMUSK; Manley, Patricia, VBASPT; VAVBASPT/RO/DIR
Subject: [EXTERNAL] VA violates federal laws

President Trump,

I have had to spend hundreds and hundreds of dollars faxing information in on:

1. St Petes/Reno not retro is still not correct today concerning my VA disability pay because of continuing to input my past dependents wrong PER DFAS/CRSC, my 3 kids DEA retro pay, my PTSD not being combat coded back to 1/1/2007, and customized not being combat coded per BVA because St Pete's RO.
 - a. BVA special team put full/CH 35 yet, St Petes and Reno both changed it in their audits deleting that in comments.
 - b. St Petes/Reno both wrongly dropped my authorized dependents multiple times, disregarding the 4 excels/multiple word documents that I made for them to help them complete my retro disability and 3 dependents DEA retro by federal law. DFAS/CRSC verified problem is VA disability.
 - c. St Petes RO has failed per BVA write up from 4/2018 states to rule on my dystonia combat code appeal filed in 2016. Dystonia is secondary to my terminal lung disorder from Iraq/Afgh which is combat coded already.
 - d. St Pete's/Reno has failed to retro my combat code my PTSD back to 1/1/2007, by 4/2018 BVA appeal win, BECAUSE DFAS/CRSC both told me so.
 - e. Ms. Manley was last assigned to my disability retro. I have redone excels to met her needs, I have refaxed just how St Petes/Reno got their audits wrong from May 2018 - present, yet no one cares.
DFAS told me, St Petes has NOT reinput my info since their Sep 2018 inputs which were wrong. I said that all along...the VA computer cannot get it right in the VA VA employees inputting do it wrong time/time again.
 - f. And as of today, St Petes RO is EXACTLY as I told the BVA BVA judge 2/2018 that St Petersburg will NEVER follow federal laws and VA standards to do the right thing before I die.
2. And then, St Petes RO did not direct DEA information, instructions nor authorization per federal law and BVA federal judges direction to do so.
Instead, St Petes changed the BVA initial audit, deleting full and DEA.
St Petes directs 674 forms.

5 federal VA employees deny DEA entitlements and direct 674 forms for 18 mths. And, I reported 6 dependents, 3 college since 2016 in multiple appeals to include 2018, notified prior to 1 year VA disability had not authority DEA per BVA, and submitted the documentation. Muskogee has received all 3 DEA retro kids (Chris, Caleb, and Matt) applications per 38 CFR, 3110, 3115, CH 35, etc, parents/sponsors file/parents are to be paid yet...all 3 not progressed per Ms Rasmussen breaking federal laws now.

Multiple federal court cases were provided where the Sec of the VA and or Muskogee specifically denied and was found to be in violation of breaking federal laws.

And still, none of these 3 retro DEA have been processed to date.

Christopher's 2nd application faxed last week to DC BVA fax since the 1st application in Feb was denied action by Ms Rasmussen's letter. And, still no action to date. Retro 14 YEARS after the fact authorization due to St Pete's shredding my claim and this is the treatment my family gets?

HERE is Matthew's 2nd application is attached since Ms Rasmussen denied processing the 1st application in Feb sent to DC BVA fax was denied by Ms Rasmussen's letter. And still no action to date.

14 years...

And, Ms Rasmussen denied processing Caleb's application too.

3. Sir, the VA pushes Veterans to give up to save their \$200+ billion dollar budget, to repeatedly have Vets take themselves out on VA campuses so the world knows who failed them repeatedly by breaking laws, and or continues the deny until you die. There is no reason that a system we pay for to serve continues to pick and choose what laws and standards they want to follow today. Just how many more years, how many more appeals, how much more time, money or faxes or excels have to be made for the VA to actually read and follow the information for entitlements?

4. St Petes just sent me a letter 2 days ago saying...their audit was right 9/2018...a lie. We called...no answer, issue closed.

APPARENTLY...that person who typed this 3/2020 letter from St Petes didn't read my record....FROM DC....stating the VA is to contact me by EMAIL. Cellphones are difficult for me to force out air and there is no miscommunication.

5. I sent you all this information to include names, dates, timeline, etc. Lost my health, job, home, family, finances, dreams, and life. How much long Sir do my family and I have to be denied full, earned entitlements?

Please resolve these issues.

Respectfully

MSgt Sandra Thornton

USAF 21 yrs retired

Iraq/Afgh

Terminally ill Wounded Warrior

From: Sandra Thornton <angelsallarounds@hotmail.com>

Sent: Friday, February 28, 2020 7:58 AM

To: The White House <reply-ff251178716d-357_HTML-44931805-6417559-3675@mail.whitehouse.gov>; Eric Trump <reply-18500-16_HTML-32943693-10964169-3570@campaigns.rnchq.com>; Donald J. Trump <reply-17143-16_HTML-32943693-10964169-6344@campaigns.rnchq.com>

Cc: VAVBAWAS/CO/Office of the USB VBA <OfficeoftheUnderSecretaryforBenefits@va.gov>;

VAVBAWAS/AMO/DIR <dir.vbaamo@va.gov>; VAVBAWAS/AMO/COMMS <Appeals-

Comms.AMO@va.gov>; VA Accountability Team <vaaccountabilityteam@va.gov>; Willie.Clark@va.gov

<Willie.Clark@va.gov>; Michael.Pence@mail.house.gov <Michael.Pence@mail.house.gov>; Robert.Wilkie@va.gov <Robert.Wilkie@va.gov>; Bevins, Debi <debi.bevins@va.gov>; Kristen.Sellars@mail.house.gov <Kristen.Sellars@mail.house.gov>; VHA Client Services Response Team <VHAClientServicesResponseTeam@va.gov>; Hannity@foxnews.com <Hannity@foxnews.com>; pkime@militarytimes.com <pkime@militarytimes.com>; Rasmussen, Deena L., VBAMUSK <deena.rasmussen@va.gov>; Manley, Patricia, VBASPT <Patricia.Manley@va.gov>

Subject: Muskogee DEA violates federal laws

President Trump,

Here it is in black and white...Muskogee VA DEA knowingly violating the federal BVA Judge's retro ruling 4/2018 with court cases referenced; violating federal laws/court precedences below stating parents (ie. Sponsors - me) are entitled to retro; and federal laws stating the parent (ie me) is to be paid.

VA disability directed 674 forms, not DEA forms in 2018, even though 2017, 2018 multiple NODs stated dependents and 3 college; and 12/2017 Dept of Defense letter verified dependents; and transcripts were supplied, etc.

It is almost 2 years later waiting on my correct VA disability retro because VA posted 49 Master's level classes as Comp & Pen between 7/2010-7/2014 versus Voc Rehab Stipend AND because the St Pete's/Reno VA disability reps processing my retro never advised DEA forms/process nor notification; and now Ms Rasmussen refuses to process my 3 RETRO back 14 years dependent sons/step son applications.

And please note, DEA also is not reading information provided. DEA has failed to acknowledge 3 applications twice now (Chris, Matt, and Caleb). On the applications, it states...Christopher and Matthew are my biological sons - not step sons. Caleb was my only dependent step son for 5 full years (1 year in HS, 4 years college). AND, this being 14 years retro will not fit the normal application for a current college dependent to check off the columns - it requires a system to follow laws, have competence and empathy for the Veteran after VA federal employees broke federal laws/VA standards by shredding my case 14 years ago.

This just reaffirms the VA unwritten Core Value - humiliate, refuse to valid, break federal laws to save a \$1 in our \$220 billion dollar machine for bonuses, and...as always deny "earned, authorized, benefits and entitlements until we die."

I will fax emails/pages to you. And, I have audios.

Please assist Sir. I thank you for your service to our great nation.

Respectfully,

Sandra Thornton
MSgt 21 yrs
Iraq/Afgh
Terminally ill Wounded Warrior

From: Sandra Thornton <angelsallaroundus@hotmail.com>

Sent: Monday, February 24, 2020 3:33:17 PM

To: Rasmussen, Deena L., VBAMUSK <deena.rasmussen@va.gov>; Robert.Wilkie@va.gov <Robert.Wilkie@va.gov>; Willie.Clark@va.gov <Willie.Clark@va.gov>; Bevins, Debi <debi.bevins@va.gov>; VAVBAWAS/AMO/DIR <dir.vbaamo@va.gov>; VAVBAWAS/CO/Office of the USB VBA <OfficeoftheUnderSecretaryforBenefits@va.gov>; VAVBAWAS/AMO/COMMS <Appeals-Comms.AMO@va.gov>; VA Accountability Team <vaaccountabilityteam@va.gov>; VHA Client Services Response Team <VHAClientServicesResponseTeam@va.gov>; Michael.Pence@mail.house.gov <Michael.Pence@mail.house.gov>; Eric Trump <reply-18500-16_HTML-32943693-10964169-3570@campaigns.rnchq.com>; Donald J. Trump <contact@victory.donaldtrump.com>; angelsallaroundus@hotmail.com <angelsallaroundus@hotmail.com>

Cc: Hannity@foxnews.com <Hannity@foxnews.com>; pkime@militarytimes.com <pkime@militarytimes.com>

Subject: Final DEA Retro

President Trump, Vice President Pence, and Secretary Wilkie,

1. The Federal VA BVA Judge AWARDED my retro pay for 3 past college dependents in April 2018 after VA disability at St Pete's shred my claim 12 years prior.
 - I was "not" afforded timely adjudication for my 100% rating to include all of my 6 dependents, 3 of which went to college.
 - **Per 38 U.S.C. Code 3531, Chapter 35, under the Educational Assistance Allowance, the Secretary shall, in accordance with the provisions of Chapter 35 of this title, pay to the PARENT of each eligible person who is pursuing a program of education on behalf of such an eligible person, an educational assistance allowance to meet, in part, "the expenses of the eligible person's subsistence, tuition, fees, supplies, books, equipment, and other educational costs".**
 - **"I paid for these 3 college dependents" because of the VA employee shredding my file, not the VA .**
 - Thus, VA DEA at MUSKOGEE should "**not**" have any problem with my retro submitted informal request which was submitted within 1 month on NOD 5/2018 after the BVA Appeal decision 4/2018, **nor** should DEA have any issue 12 years after the fact with me filling out the official applications with "for" since this retro DEA pay is actually due to me since I paid for their colleges 2007-2013 (until age 26 and or termination of dependency statuses), **nor** should DEA expect to complete the normal DEA processing of these applications because this is retro from 2007-2013 due to VA employees breaking federal laws/VA standards, and lastly because after this 4/18 BVA decision/NOD 5/18 with 3 college students reported/seeing another government entity - the Department of Defense Verification letter dated 12/2017 - validating all these dependents continued as dependents due to college - St Petes VA disability handler of processing this retro did **not** advise me Florida Dept of Veteran Affairs to complete the DEA 22-5490, she instructed to complete VA 21-674 forms. Thus, **St Petes RO and Reno RO failed** yet again...because under the Veteran's Claim Assistance Act (VCAA), 38 U.S.C. 5100, 5103a, 5106, 5107, 5126 have requirements to notify me - I found out by a Marine Veteran,

lawyer, and who wrote your VA standards that St Petes was breaking federal law yet again.

- I continued to report to BVA May 2018 - Sep 2019, my retro pay was not correct for my retirement/all of my dependents. Within weeks Oct 2018, Panama City hit with Category 5, 165 MPH Hurricane Michael, we had nothing in Panama City - sleeping in my car on 2 machines, no phones or computers, gas, food, shelter, hospitals, etc.
- Jul 2019 and Sep 2019, I stated again - my retro was still not correct.
- I had Iraq/Afgh surgeries 6, 7, 8 plus 3 procedures and my recovery did not go well. I was bedridden 5-6 months with no comm.
- So, I still have no computer but the library is now up and running better so, I contacted Mr. Clark again in 2020...this is my 4th/final VA excels for retro pays (DEA and disability had to be separated I was just told and the VA computer is falsely reporting 52 repeat mthly disability payments between 7/2010 - 8/2014 which are false/still have not been removed off of my VA EBenefits files and or the VA had a rogue VA finance employee for 4 years).

2. Title 38, section 3680g, **the Secretary shall accept certification of DEA made by the Veteran.**

3. 38 USC, 501, **Secretary has the authority to carry out laws to include manner or form adjudication/awards** (Title 5, 552, 553, and Public Law 102-83)

4. **Federal laws and Case Precedence establish my entitlements/retro:**

38 USC 3500, 3501, 5113 Secretary has decision to award, 5100, 5102, 5103, 5103A, 5106, 5107 Veteran has benefit of the doubt, 5126, 501, 3511, 3512, 5113 P/T, formal/informal claims will be accepted, sought retro within 1 year (formal/informal), 3501

38 CFR 3.807, 3.102 in favor of Veteran, 3.159, 3.156, 3.326, 3.326a, 21.4135d, 21.1030 informal or formal application received, 21.1029, 21.3021 adj effective dates, 21.3020, 21, 21.3135 step parent, 21.4131, 20.302, 21.1033, 21.3030

VCAA requirements to notify

Title 5, 552, 553

Public Law 102-83, 106-419, 107-14, 107-330, 85-857, 106-475, 109-461 Section 3501, 114 Stat 2096, 114 Stat 1832,

CH 35, 24.3041, VA is to expedite payment

5 USC 610-612, Regulatory Flexibility Act

5 USC 553 delayed effective date

10 USC 21.4131, 21.3041

5. **These are ALL Retro cases won:**

THORNTON v VA (me 4/2018 - 12 years)

Sharp v Shiniski

Muskogee Cit NR 0814380, RO denied claim/then failed timely notices, Muskogee denied retro, BVA appeal won

US Court of Appeals Pelegrini v Principi RO denied eligibility, retro won

Miley v Principi, retro won

Hayre v Principi, retro won

Donovan v Gober, retro won

Fenderson v West, retro won

Buffalo VA Cit NR 0616803 RO did not notify until after 1 year, BVA appeal won
Valiao v Principi, reaffirmed RO should "not" attempt to change the boards decision (just as St
Petes told me DEA did not apply because my dependents weren't currently in college, I pointed
out this was "retro" and still I was told by VA St Pete's Precious was complete the 674 forms.
Bernard v Brown, appeal won, ABSENCE of notice - caused harmful error
Buffalo Cit NR 1333020, retro won

6. My DEA Retro Pay is:

For Chris \$42,212

For Caleb \$41,773

For Matt \$33,648

Total: \$117,633.00 RETRO DEA DUE TO ME (2007-2013 to age 26 and or dependence ended
prior)_

7. It took 12 years waiting for justice.

8. It is now year 14 because St Petes did "not" follow the federal BVA judge's order.

9. President Trump and Secretary Wilkie, please direct DEA to authorize my 3 dependents retro
back pay to me today since I paid for all of these dependents myself from 2007-2013.

10. Mr. Clark and Ms. Rasmussen, I would appreciate an update please on Secretary Wilkie
waivering this normal process/honoring my earned benefits/entitlements by federal laws 14
years after the fact to retro me under the bizarre circumstances/since my case is supposed to
be expedited. My records are correct unlike 52 duplicate/fake mthly disability pay posting on
my VA EBenefits files 7/2010-8/2014. I am truly exhausted....this is the 4th time, I have had to
rework this for the VA, **this is the final excels**. I am hurting, I will get my son to fax paper
disability excels/this DEA excels documents to you tomorrow. I will confirm my appointment
with the Secretary when I get online.

Thank you.

Respectfully,

MSgt Sandra Thornton

USAF 21 years

Iraq/Afgh

Terminally ill Wounded Warrior

From: Sandra Thornton <angelsallaroundus@hotmail.com>

Sent: Friday, February 21, 2020 2:33 PM

To: Rasmussen, Deena L., VBAMUSK <deena.rasmussen@va.gov>; Robert.Wilkie@va.gov
<Robert.Wilkie@va.gov>; Willie.Clark@va.gov <Willie.Clark@va.gov>; Bevins, Debi
<debi.bevins@va.gov>; Donald J. Trump <reply-17143-16_HTML-32943693-10964169-
6344@campaigns.rnchq.com>; Sandra Thornton <angelsallaroundus@hotmail.com>;
VAVBAWAS/AMO/DIR <dir.vbaamo@va.gov>; VAVBAWAS/CO/Office of the USB VBA
<OfficeoftheUnderSecretaryforBenefits@va.gov>; VAVBAWAS/AMO/COMMS <Appeals-
Comms.AMO@va.gov>; VA Accountability Team <vaaccountabilityteam@va.gov>; VHA Client Services
Response Team <VHAClientServicesResponseTeam@va.gov>; Michael.Pence@mail.house.gov
<Michael.Pence@mail.house.gov>; Donald J. Trump <contact@victory.donaldtrump.com>; Eric Trump
<reply-18500-16_HTML-32943693-10964169-3570@campaigns.rnchq.com>; Donald J. Trump
<contact@victory.donaldtrump.com>

Cc: Hannity@foxnews.com <Hannity@foxnews.com>; pkime@militarytimes.com

<pkime@militarytimes.com>; Sandra Thornton <angelsallaroundus@hotmail.com>

Subject: DEA

President Trump, Vice President Pence, and Secretary Wilkie,

I have waited 5,100+ days (14 years) for my 1- 3 DEA dependents...Chris, Matt, and Caleb retro pay due to me and retro VA disability pay due to me because of St Pete's. And 1 year 10 mths, St Pete's not following the BVA just to combat code an item since 2015 rating/BVA appeal 4/18 decision.

Per US Code 38, Section 3531, CH 35, the Secretary of the VA directs the RETRO DEA to me because I was the parent/step parent and or guardian. I paid for these kids due to VA St Petersburg's employees breaking federal laws/VA standards. 551 U.S. at 665, Sect 1115 and Section 1114, SHARP v SHINSEKI and BROWN v. GARDNER, entitlements to additional compensation for dependents, proof submitted within 1 year it was, in favor of the Veteran, and VETERANS could be ARBITRARILY DISADVANTAGED based on DELAYS IN ADJUDICATION that are BEYOND THEIR CONTROL...like shredding/denying my dependents which got us here today.

I am officially requesting the Secretary of the VA to direct VA DEA to FOR GO the regular application process (which will NOT work in this situation of RETRO 14 years AFTER the fact) to accept my documents signed "FOR Chris, Matt, and Caleb" since I was the legal/entitled sponsor/parent/step parent since retro pay is coming to ME for the lost benefits/entitlements which I paid for when the VA illegally shred my claim/repeatedly denied my dependents adds, since their was a divorce in 2013, etc. I have sent in DEA forms, Chris/Matt's transcripts (2 classes to add amend), DoD Verification, 674s, 21-686c, etc multiple times. I told the BVA judge 2 years ago, the VA will never do the right thing by me. I asked after going through hell with St Petes, bring common sense to fixing this 14 year retro...but, a billion dollar system who has the option to cut the red tape in other situations won't when you should. I ask you to accept my submitted forms, my this coming Monday excel document validating the exact pay for all 3 kids due to me, and just authorize paying me/let's end this part of the BVA decision, it has been almost 2 years for accurate retro by federal laws/court cases on record.

The VA has just requested \$240.3 BILLION dollar budget this year and can use good judgement to finally help me after years of wrong doing.

You see, I lived my whole life serving and with core values. I served her honorably for over 21 years in DoD and served in the VA 6.5 years. I gave everything to this country and it was my honor but, what the VA has done here for 14 years is illegal and a disgrace. Your VA employees had a duty to not shred my claim and deny, not follow, and ignore...a duty.

In serving our nation, I ensured laws, standards, tried to educate, tried to correct, and if not I reported to leadership. When leadership ignored, let people die, and broke laws I went to Congress and the media.

I helped Military Times blow the whistle on the Department of Defense in Nov 2015 for purportedly keeping exposures out of deployment records (I discovered);

I came to DC with Lauren Price Nov 2013, met with the Chairman of Veteran Affairs Committee DOMA, met with Senator Rubio/Rep Bilirakis, took 50 YEARS of repeated VA IG reports of St Pete's breaking federal laws/VA failed standards which kicked off 2 years of televised hearings (we discovered);

I helped coordinate 50 states, House/Senate approved and President Obama signing the Airborne Registry;

And I reported to Congress/the media the Secretary Shinseki Office directed a VA IT Office in DC across from the White House to tap 42 VA Whistleblowers in/outbound emails, etc in 2015 under SEC Internal Divert all because we tried to fix the VA/support what you say the VA stands for. You tracked us for reporting employees breaking laws/standards. And I should know, that screen shot was my VA computer screen.

So again, the VA here has to acknowledge this is a 14 YEAR RETRO to me case on my 3 dependents, every item on a current new DEA application cannot happen here, and you should all have a realize cutting red tape because of your employees breaking the laws, severely damaged me/broke me/my family, do your duty to complete the BVA Judge's order with common sense please.

These 3 DEA retro is due to me.

I was the sponsor/parent.

It is 14 years later.

I paid for all of them.

You have the DoD dependents validating college continued.

You have 2 boys transcripts too since 2017.

Since all 3 retros are repaying me per US Code 38, the VA DEA should accept my "for" forms, and authorize all 3 retros to me asap.

I am sending the excel word doc Mon for your records to help show you the amounts are accurate to proceed.

I will send excel word docs on 3 kids Monday. I would like to know by Tuesday if the Secretary is going to honor my request on how the DEA will proceed with this 14 year retro to me.

Thank you.

Respectfully

S. Thornton

Reminder#####

The DC VA still needs to explain WHY the VA posted "52 duplicate monthly disability payments in EBenefits on my name from 7/2010 - 8/2014. " I faxed the proof to you on 2/11/2020 fax to BVA. I have checked with other Veterans and theirs do not reflect duplicates...so this is not a computer glitch and I never received 52 extra mths disability pays. So, the DC VA needs an investigation - either you have a creative VA finance thief or someone in the VA was purposely reflecting I was paid more than I was. I want a written explanation. Seeing that explains why you still haven't paid my regular retro VA disability pay yet from 5/2018.

From: Rasmussen, Deena L., VBAMUSK <deena.rasmussen@va.gov>

Sent: Friday, February 21, 2020 9:37:29 AM

To: Sandra Thornton <angelsallarounds@hotmail.com>

Subject: RE: Your recent inquiry to VA

Dear Ms. Thornton,

After I sent you the email this morning, I was forwarded documents you sent with the inquiry which I was assigned.

No action can be taken on the applications for Caleb and Matthew since you signed them on behalf of your dependents who are over the age of 18. Your dependents will need to submit a signed VA Form 22-5490 requesting benefits under the Dependent's Educational Assistance program. Once VA receives their signed applications, a decision will be made as to the dependents' eligibility under this program.

Your dependents may also apply online at www.vets.gov and submit a VA Form 22-5490 online. This is a secure website and the applications will be electronically transmitted to the VA.

Thank you for your service,

Deena Rasmussen
Supervisory Veterans Claims Examiner
Education Call Center

From: Sandra Thornton <angelsallaroundus@hotmail.com>
Sent: Friday, February 21, 2020 9:27 AM
To: Rasmussen, Deena L., VBAMUSK <deena.rasmussen@va.gov>; Sandra Thornton <angelsallaroundus@hotmail.com>; Manley, Patricia, VBASPT <Patricia.Manley@va.gov>; Clark, Willie, VBAVACO <Willie.Clark@va.gov>; The White House <reply-ff251178716d-357_HTML-44931805-6417559-3675@mail.whitehouse.gov>; Michael.Pence@mail.house.gov; Kristen.Sellars@mail.house.gov; VAVBAWAS/AMO/DIR <dir.vbaamo@va.gov>; VAVBAWAS/CO/Office of the USB VBA <OfficeoftheUnderSecretaryforBenefits@va.gov>; Bevins, Debi <debi.bevins@va.gov>; Wilkie, Robert L., Jr. <Robert.Wilkie@va.gov>; VAVBAWAS/AMO/COMMS <Appeals-Comms.AMO@va.gov>; VA Accountability Team <vaaccountabilityteam@va.gov>; Donald J. Trump <reply-17143-16_HTML-32943693-10964169-6344@campaigns.rnchq.com>; Eric Trump <reply-18500-16_HTML-32943693-10964169-3570@campaigns.rnchq.com>; VHA Client Services Response Team <VHAClientServicesResponseTeam@va.gov>; VAVBASPT/RO/DIR <DIR.VBASPT@va.gov>; Ogilvie, Brianne, VBAWASH <Brianne.Ogilvie@va.gov>; McLenachen, David, VBAWASH <David.McLenachen@va.gov>; Quill, Joshua J., VBAVACO <Joshua.Quill@va.gov>; VAVBA/Southeast <Southeast.VAVBA@va.gov>; VAVBASPT/RO/INQUIRY TEAM <INQUIRYTEAM.VBASPT@va.gov>; Tallerico, Kristina, VBAREN <Kristina.Tallerico@va.gov>
Cc: Hannity@foxnews.com; pkime@militarytimes.com; Sandra Thornton <angelsallaroundus@hotmail.com>
Subject: [EXTERNAL] Re: Your recent inquiry to VA
Importance: High

Ms. Rasmussen,

ALL my past dependents kids (this is RETRO 1/1/2007 to age 26) Chris Boe, Matt Boe, and now...thanks to the VA ex-step son Caleb Baty were faxed into the BVA 2/11/2020, 42 pages.

WHY you may ask since no one has filled you in?

1) St Pete's was found to have shred my 2006 claim, along with others.
2) Federal/State VA reps repeatedly denied entering my steps in as dependents.
3) It took 12 years (5,100+ days) of losing everything and STILL living in hell because of St Pete's BEFORE a BVA Judge apologized in 2/2018 hearing, 4/18 awarded RETRO back to 1/1/2]07 on VA pay, awarded ALL (6) past dependents, awarded US Code CH 35 on my 3 past dependents because 4 medical specialists 100% permanent and total, and I am terminally ill from Iraq/Afgh.
4. It is NOW 1 year, 9 months later, that I have been telling the White House, the VA Secretaries, the Undersecretary, BVA, St Petes, Reno, etc that I backpay is wrong.
You see, NO one has followed the federal BVA Judge's order completely.
Precious in St Petes told me, DEA didn't apply because I had no kids in college. Thus, the different reps handling my retro instructed me x 3 to complete the 674 forms (I attached the email traffic again yesterday) thus, not only has my VA disability pay, my minor dependents pay was wrong because VA reps were not inputting the data correctly, and because NO VA rep instructed me to do any DEA forms. A Marine, Veteran, lawyer, who WROTE VA standards informed me these reps who handled my award have all NOT followed the federal Judge's order were in fact all breaking the law.
I have provided the DEA forms, 674 forms, DoD certification of dependents as minors and which verifies 3 continued IN COLLEGE dated 12/2017, my letters, transcripts on my 2 biological children, 1 and 2 excel word documents already on everything broken down.
The first excel 8/2018 was with 674 rates because VA instructed wrong and only to age 22, both wrong. The second excel word docs 2/2020 after Marine Veteran lawyer who worked in DC informed me on DEA does apply until age 16.

And 2 days ago,

Ms. Manley nicely explained disability and DEA are 2 diff pots of monies so the issues have to be divided. My son and I stayed up on night Wed night dividing the two issues, correcting a couple of minor adds on my end, and correctly numerous major errors by St Petes, Reno, and UnderSecretary to ensure 1 last final and accurate break down so President Trump can direct the Secretary to end this now 14 year journey of St Petes hell.

I was exhausted yesterday being up all night doing this, I went through a CAT Hurricane in Oct 2018 so I have to go to the library to update the excel word documents with break down each year, month, dependents, my pay, what I should have been paid, and was IS due to me.

I wrote the President, etc and asked him to direct this 14 year RETRO DEA process be simplified since you have the forms, since the shredding of my file, I PAID for all these past dependents and under Sharp vs Schincki my case was not timely adjudicated, and federal law under 38 Series, Section 3150, CH 35, states the Secretary WILL PAY THE PARENT. Because of my terminal illness and lost my health, my job, my family to including my marriage and 3 steps in Sep 2013, my home, and living in a car on 2 machines repeatedly (thanks to the VA) my case has been expedited. The step son graduated UGA 5/2012, I dropped him as a dependent 4/2012 because he was self medicating on prescription medication, if you absolutely can't take my honor/honesty and Dept of Defense 12/17 letter verifying he continued as a dependent due to college, I will try to get his transcripts since this RETRO IS 6 YEARS LATE FOR HIM or someone with common sense can stop this extra red tape under these EXTRAORDINARY CIRCUMSTANCES OF JUSTICE 14 YEARS LATE due to VA employees breaking countless federal laws/standards.

I will finish this FINAL document to lay it out for you and Ms Manley by MONDAY to BVA fax #.

VA Disability RETRO STILL DUE TO ME...
\$35,090.15

DEA TO ME...

CHRIS \$42,212

CALEB \$41,773

MATT \$33,648 (I have 2 classes, age 25, to add to DEA form - I was sending update fax today and).

And because of VA broken laws and lies, DC has agreed all correspondence will be in writing on email. So if you have questions or clarification, please email me.

Note: I was in CH 31 Voc Rehab for a couple of years. I market no on kids forms because with this lower oxygen level, I honestly don't remember any thing for them. But, please double check me for any small monetary on my 2 biological kids Chris/Matt under CH 31 Ms. DEA because I don't want anything that is not accurate given to me.

Thank you
Sandra Thornton
USAF 21 yrs retired
Iraq/Afgh
Terminally ill Wounded Warrior

From: Rasmussen, Deena L., VBAMUSK
<deena.rasmussen@va.gov<mailto:deena.rasmussen@va.gov>>
Sent: Friday, February 21, 2020 7:29:20 AM
To: angelsallaroundus@hotmail.com<mailto:angelsallaroundus@hotmail.com>
<angelsallaroundus@hotmail.com<mailto:angelsallaroundus@hotmail.com>>
Subject: Your recent inquiry to VA

Dear Ms. Thornton,

I tried reaching you by phone several times. You did not answer and I was unable to leave a voicemail because the voice message box was full. This email is in response to your inquiry about your children's education benefits under the Dependents Educational Assistance (DEA) Program.

The evidence in your Compensation file shows you submitted multiple applications on a VA Form 21-686c, Application Request to Add And/Or Remove Dependents and VA Form 21-674 Report of School Attendance. These requests are not an application for Dependents Educational Assistance. I could not locate a file or an application for education benefits for any of your children. Your children can apply for DEA at www.vets.gov<<http://www.vets.gov>> by completing a VA Form 22-5490, Application for Dependents Education Assistance Program. Applications completed at this website are electronically submitted to VA via a secure website.

If you have any questions, you may reach me at (918) 781-5743.

Thank you for your service,

Deena Rasmussen
Supervisory Veterans Claims Examiner
Education Call Center

BUA Appeal Win 4/18 Retro CH 35

Covers 08/09-05/12

OMB Approved No. 2900-0098
Respondent Burden: 45 minutes
Expiration Date: 10/31/2021

Department of Veterans Affairs

VA DATE STAMP
(For VA Use Only)

DEPENDENTS' APPLICATION FOR VA EDUCATION BENEFITS
(Under Provisions of chapters 33 and 35, of title 38, U.S.C.)

INTERNET VERSION AVAILABLE - You may complete and submit your application online at: www.benefits.va.gov/gibill.

Request to Opt-Out of Information Sharing With Educational Institutions

By checking the box, I CERTIFY THAT THE DEPARTMENT OF VETERANS AFFAIRS (VA) does not have my permission to share information about my veterans' education benefits with any educational institution. I understand that sharing my information with my school is intended to support the certification process and that "opting-out" may delay that process. See Information and Instructions on Page 7 for more information.

PART I - APPLICANT INFORMATION

1. SOCIAL SECURITY NUMBER: 590-04-0299
2. SEX OF APPLICANT: MALE FEMALE
3. DATE OF BIRTH: 25 September 1990

4. NAME (First name, middle initial, last name): Matthew R Boe

5. CURRENT MAILING ADDRESS (Number and street or rural route, city or P.O., State and ZIP Code): 4701 Scots Briar Lane, Fort Worth, TX 76137

6. TELEPHONE NUMBER(S) (Including Area Code)
PRIMARY: 850 630 4348
SECONDARY:

7. E-MAIL ADDRESS: matthewboe@yahoo.com

8. DIRECT DEPOSIT (Attach a voided personal check or provide the following information. See instructions for additional information.)

ROUTING OR TRANSIT NUMBER: 263183175
ACCOUNT TYPE: CHECKING SAVINGS
ACCOUNT NUMBER: 0000271828971

9. PLEASE PROVIDE THE NAME, ADDRESS, AND TELEPHONE NUMBER OF SOMEONE WHO WILL ALWAYS KNOW WHERE YOU CAN BE REACHED

A. NAME: Sandra D. Thornton
B. ADDRESS: P.O. Box 617, Paramaribo, FL 32402
C. TELEPHONE NUMBER (Include Area Code): 850 814 5105

PART II - QUALIFYING INDIVIDUAL INFORMATION

10. NAME OF QUALIFYING INDIVIDUAL (PARENT OR SPOUSE) ON WHOSE ACCOUNT BENEFITS ARE BEING CLAIMED (First name, middle initial, last name): Sandra Dee Thornton

11. SOCIAL SECURITY NUMBER OR VA FILE NUMBER: 340-60-7678
12. BRANCH OF SERVICE: USAF
13. DATE OF BIRTH: 03/08/61

14A. DID PARENT OR SPOUSE DIE WHILE SERVING ON ACTIVE DUTY? YES NO (If "Yes," is checked complete Item 14B) (If "No," is checked then you do not qualify for the Fry Scholarship)
14B. DATE OF DEATH: N/A
14C. DATE LISTED AS MISSING IN ACTION OR P.O.W.: N/A

15. IS QUALIFYING INDIVIDUAL (PARENT OR SPOUSE) ON ACTIVE DUTY? YES NO 2 yrs Active Duty Iraq/Afghanistan 100% RT 1/1/08 Terminally Ill

16. DO YOU (APPLICANT) OR THE QUALIFYING INDIVIDUAL (PARENT OR SPOUSE) HAVE AN OUTSTANDING FELONY AND/OR WARRANT? YES NO

PART III - RELATIONSHIP AND BENEFIT INFORMATION

17. YOUR RELATIONSHIP TO QUALIFYING INDIVIDUAL (Check only one)
 SPOUSE/SURVIVING SPOUSE (Please complete only Section I on page 2, and then proceed to Part V)
 CHILD/STEPCHILD/ADOPTED CHILD (Please complete only Section II on page 2, and then proceed to Part V)

SECTION I - SPOUSE/SURVIVING SPOUSE

18. IS A DIVORCE OR ANNULMENT PENDING TO THE QUALIFYING INDIVIDUAL? YES NO
19. IF YOU ARE THE SURVIVING SPOUSE, HAVE YOU REMARRIED? YES NO (If "Yes," please provide date of remarriage) N/A

SECTION I - SPOUSE/SURVIVING SPOUSE (Continued)

20. SPOUSE/SURVIVING SPOUSE SELECT THE BENEFIT THAT YOU ARE APPLYING FOR BELOW:

IMPORTANT ▶

PLEASE CAREFULLY READ THE INFORMATION AND INSTRUCTIONS ON PAGE 5, ITEM 20 BEFORE SELECTING BOX "A" OR "B" BELOW REGARDING THE BENEFIT YOU ARE APPLYING FOR. THE INFORMATION AND INSTRUCTIONS ON PAGE 5 ALSO PROVIDE LINKS TO VA WEBSITES WHERE YOU WILL BE ABLE TO COMPARE "DEA" AND "FRY" BENEFITS. YOU WILL ALSO FIND OTHER ELIGIBILITY RELATED INFORMATION THERE.

A. AS A SPOUSE OR SURVIVING SPOUSE BASED ON 100% PERMANENT AND TOTAL DISABILITY, SERVICE CONNECTED OR LINE OF DUTY DEATH, I AM APPLYING FOR CHAPTER 35 - DEA BENEFITS.

B. AS A SURVIVING SPOUSE BASED ON LINE OF DUTY DEATH AFTER SEPTEMBER 10, 2001, I AM APPLYING FOR CHAPTER 33 - FRY SCHOLARSHIP BENEFITS.

NOTE - BY CHECKING THIS BOX I ACKNOWLEDGE THAT I UNDERSTAND THIS ELECTION IS **IRREVOCABLE** AND MAY NOT BE CHANGED.

NOTE - BY CHECKING THIS BOX I ACKNOWLEDGE THAT I UNDERSTAND THIS ELECTION IS **IRREVOCABLE** AND MAY NOT BE CHANGED.

SECTION II - CHILD/STEPCHILD/ADOPTED CHILD

21. CHILD/STEPCHILD/ADOPTED CHILD SELECT THE BENEFIT THAT YOU ARE APPLYING FOR BELOW:

IMPORTANT ▶

PLEASE CAREFULLY READ THE INFORMATION AND INSTRUCTIONS ON PAGE 6, ITEM 21 BEFORE SELECTING BOX "A" OR "B" BELOW REGARDING THE BENEFIT YOU ARE APPLYING FOR. THE INFORMATION AND INSTRUCTIONS ON PAGE 6 ALSO PROVIDE LINKS TO VA WEBSITES WHERE YOU WILL BE ABLE TO COMPARE "DEA" AND "FRY" BENEFITS. YOU WILL ALSO FIND OTHER ELIGIBILITY RELATED INFORMATION THERE.

A. I AM APPLYING FOR CHAPTER 35 - DEA BENEFITS.

B. I AM APPLYING FOR CHAPTER 33 - FRY SCHOLARSHIP BENEFITS.

NOTE - BY CHECKING THIS BOX I ACKNOWLEDGE THAT I UNDERSTAND THIS ELECTION IS **IRREVOCABLE** AND MAY NOT BE CHANGED.

NOTE - BY CHECKING THIS BOX I ACKNOWLEDGE THAT I UNDERSTAND THIS ELECTION IS **IRREVOCABLE** AND MAY NOT BE CHANGED.

Important - If your parent died in the line of duty prior to August 1, 2011, you may apply for **both** DEA and Fry Scholarship benefits. If you are eligible for both Chapter 35 (DEA) and Chapter 33 (Fry Scholarship) benefits and you would like to use the Chapter 35 benefit first, check the box below.

Important - If your parent died in the line of duty prior to August 1, 2011, you may apply for **both** DEA and Fry Scholarship benefits. If you are eligible for both Chapter 35 (DEA) and Chapter 33 (Fry Scholarship) benefits and you would like to use the Chapter 33 benefit first, check the box below.

CHAPTER 35 - DEA

CHAPTER 33 - FRY SCHOLARSHIP

IMPORTANT: If you are over the age of 18 once you receive either the DEA or FRY SCHOLARSHIP benefits, you will no longer receive payments of Dependency and Indemnity Compensation (DIC) or Pension and you may no longer be claimed as a dependent in a Compensation claim. If you are under the age of 18, on your 18th birthday you will lose eligibility for DIC or Pension payments and you will no longer be claimed as a dependent in a Compensation claim.

CAREFULLY READ THE INFORMATION AND INSTRUCTIONS ON PAGE 6, ITEM 22 BEFORE COMPLETING THE ELECTION BOX BELOW. YOU ARE STRONGLY ENCOURAGED TO DISCUSS YOUR ELECTION WITH A VA COUNSELOR.

22. I CERTIFY THAT I UNDERSTAND THE EFFECTS THAT THIS ELECTION TO RECEIVE DEA OR FRY SCHOLARSHIP BENEFITS WILL HAVE ON MY ELIGIBILITY TO RECEIVE **DIC OR PENSION** BENEFITS *(Please read Information and Instructions Page 6 for additional information)*

YES NO

PART IV - BENEFIT AND TYPE OF EDUCATION OR TRAINING INFORMATION

23A. DATE YOU WILL BEGIN SCHOOL OR TRAINING *(MM/DD/YYYY)*

08/16/2009

23B. TYPE OF EDUCATION OR TRAINING *(Check ONE box)*

- COLLEGE OR OTHER SCHOOL
- FARM COOPERATIVE
- LICENSING OR CERTIFICATION TEST
- APPRENTICESHIP OR OTHER ON-THE-JOB TRAINING
- NATIONAL ADMISSION EXAMS OR NATIONAL EXAMS FOR CREDIT
- CORRESPONDENCE COURSE
- FLIGHT TRAINING *(Fry Scholarship only)*

23C. **[DEA ONLY]** DO YOU HAVE A MENTAL OR PHYSICAL DISABILITY FOR WHICH YOU ARE SEEKING SPECIAL RESTORATIVE TRAINING? *(See Information and Instructions, Page 6, for details regarding restorative training)*

YES
 NO

23D. **[DEA ONLY]** DO YOU HAVE A MENTAL OR PHYSICAL DISABILITY FOR WHICH YOU ARE SEEKING SPECIAL VOCATIONAL TRAINING? *(See Information and Instructions, Page 6, for details regarding special vocational training)*

YES
 NO

24. NAME AND ADDRESS OF SCHOOL OR TRAINING FACILITY (Number and street or rural route, city or P.O., State and ZIP Code)

Gulf Coast State College
5230 US-98, Panama City, FL 32401

25. SPECIFY YOUR EDUCATION OR CAREER OBJECTIVE, IF KNOWN (e.g., Bachelor of Arts in Accounting, Welding Certificate, Police Officer)

Bachelors in History

26. WOULD YOU LIKE TO RECEIVE VOCATIONAL AND EDUCATIONAL COUNSELING? (See Information and Instructions, Item 26 for more information regarding vocational and educational counseling)

YES NO

PART V - APPLICATION HISTORY

27. PRIOR TO THIS APPLICATION, HAVE YOU EVER APPLIED FOR OR RECEIVED ANY OF THE FOLLOWING VA BENEFITS? (Check all appropriate boxes)

- A. DISABILITY COMPENSATION OR PENSION
- B. DEPENDENTS' INDEMNITY COMPENSATION (DIC)
- C. VOCATIONAL REHABILITATION BENEFITS (Chapter 31)
- D. VETERANS EDUCATION ASSISTANCE BASED ON YOUR OWN SERVICE (Specify benefit(s): _____)
- E. VETERANS EDUCATION ASSISTANCE BASED ON SOMEONE ELSE'S SERVICE
SPECIFY BENEFIT(S) BY CHECKING APPLICABLE BOX BELOW AND COMPLETE ITEMS 28 AND 29
 - TRANSFERRED ENTITLEMENT
 - CHAPTER 35 - SURVIVORS' AND DEPENDENTS' EDUCATIONAL ASSISTANCE PROGRAM (DEA)
 - CHAPTER 33 - POST-9/11 GI BILL MARINE GUNNERY SERGEANT DAVID FRY SCHOLARSHIP
- F. NONE
- G. OTHER (Specify benefit(s): _____)

IMPORTANT: Complete Items 28 and 29 *only* if you checked the box for Item 27E above.

28. NAME OF INDIVIDUAL ON WHOSE ACCOUNT YOU PREVIOUSLY CLAIMED BENEFITS (First, Middle, Last)

Sandra Dee Thornton

29. SOCIAL SECURITY NUMBER OF INDIVIDUAL ON WHOSE ACCOUNT YOU PREVIOUSLY CLAIMED BENEFITS

340-60-7678

PART VI - APPLICANT'S MILITARY SERVICE INFORMATION

(NOTE: Chapter 35 benefits are not payable while an eligible person is on active duty)

30. HAVE YOU EVER SERVED ON ACTIVE DUTY IN THE ARMED FORCES? (If "No," skip to Part VII)

YES NO

31. INFORMATION ABOUT YOUR PERIOD(S) OF ACTIVE DUTY (If you need additional space use Item 37, Remarks)

| A. DATE ENTERED ACTIVE DUTY | B. DATE SEPARATED FROM ACTIVE DUTY | C. BRANCH OF SERVICE OR RESERVE OR GUARD COMPONENT | D. CHARACTER OF DISCHARGE |
|-----------------------------|------------------------------------|--|---------------------------|
| 10 October 2012 | N/A | Active USAF | N/A |

PART VII - EDUCATION, TRAINING AND EMPLOYMENT

SECTION I - EDUCATION & TRAINING

32. CHECK THE APPROPRIATE BOX AND ENTER THE DATE IN ITEM 33

- GRADUATED FROM HIGH SCHOOL DISCONTINUED HIGH SCHOOL NEVER ATTENDED HIGH SCHOOL
- EXPECT TO GRADUATE FROM HIGH SCHOOL AWARDED GED

33. DATE

12 May 2012

| 34A. TYPE OF SCHOOL | 34B. NAME AND LOCATION OF SCHOOL (City and State) | 34C. DATES OF TRAINING | | 34D. NUMBER OF SEMESTER, QUARTER, OR CLOCK HOURS COMPLETED | 34E. DEGREE, DIPLOMA OR CERTIFICATE RECEIVED | 34F. MAJOR FIELD OR COURSE OF STUDY |
|---------------------|---|------------------------|----------|--|--|-------------------------------------|
| | | FROM | TO | | | |
| HIGH SCHOOL | Bay High School | Aug 2005 | May 2009 | N/A | HS Diploma | |
| COLLEGE | Gulf Coast State College | August 2009 | May 2012 | 70 semester hrs | None | History |
| VOCATIONAL OR TRADE | | | | | | |
| OTHER (Specify) | | | | | | |

PART VII - EDUCATION, TRAINING AND EMPLOYMENT (Continued)

SECTION II - EMPLOYMENT

35. CURRENT AND PAST EMPLOYMENT

| A. EMPLOYER | B. JOB TITLE | C. NUMBER OF MONTHS EMPLOYED | D. LICENSE OR RATING |
|-------------|--------------|------------------------------|----------------------|
| | | | |
| | | | |
| | | | |

NOTE: Complete Items 36A and 36B *only* if you are a civilian employee of the U.S. Government.

| | |
|--|--|
| 36A. DO YOU EXPECT TO RECEIVE FUNDS FROM YOUR AGENCY OR DEPARTMENT FOR THE SAME COURSES FOR WHICH YOU EXPECT TO RECEIVE VA EDUCATIONAL ASSISTANCE? (If "Yes," complete Item 36B) <input type="checkbox"/> YES <input type="checkbox"/> NO | 36B. SOURCE OF EDUCATIONAL ASSISTANCE FROM GOVERNMENT EMPLOYMENT |
|--|--|

PART VIII - REMARKS, REMINDERS AND VA EDUCATION BENEFITS PAMPHLET

SECTION I - REMARKS

37. REMARKS (If more space is needed, please attach a separate sheet of paper. Be sure to include name and social security number on each sheet)

BVA Appeal Retro Chapter 35 covers Aug 2009 - May 2012
 win 4/18
 Rep MSgt Sandra Thornton # 7678 Retro DEA Dependent son

SECTION II - REMINDERS

DID YOU REMEMBER TO:


- WRITE YOUR SOCIAL SECURITY NUMBER ON EACH PAGE
- WRITE YOUR COMPLETE MAILING ADDRESS
- ATTACH SUPPORTING DOCUMENTS (e.g., birth certificate, marriage license, DD214, etc.)

SECTION III - VA EDUCATION BENEFITS PAMPHLET

38. THE MOST CURRENT INFORMATION ON VA EDUCATION BENEFITS IS AVAILABLE ONLINE AT www.benefits.va.gov/gibill. IF YOU WOULD LIKE A COPY OF THE VA EDUCATION BENEFITS PAMPHLET PLEASE CHECK THE BOX.

PART IX - CERTIFICATION AND SIGNATURE OF APPLICANT

I CERTIFY THAT all statements in my application are true and correct to the best of my knowledge and belief.

| | |
|--|-----------------------------------|
| 39A. SIGNATURE OF APPLICANT (DO NOT PRINT) SIGN HERE ► IN INK  | 39B. DATE SIGNED 00 March 2020 |
|--|-----------------------------------|

PENALTY: Willfully false statements as to a material fact in a claim for education benefits is a punishable offense and may result in the forfeiture of these or other benefits and in criminal penalties.

PART X - SIGNATURE OF PARENT, GUARDIAN OR CUSTODIAN
 (This section must be completed by the parent, guardian, or custodian if the applicant is a minor)

| | |
|---|------------------|
| 40. NAME OF PARENT, GUARDIAN, OR CUSTODIAN (First, Middle Initial, Last) (Type or print) | |
| 41. MAILING ADDRESS OF PARENT, GUARDIAN, OR CUSTODIAN Number and Street _____ Apt./Unit Number _____ City, State, ZIP Code _____ | |
| 42A. TELEPHONE NUMBER(S) OF PARENT, GUARDIAN, OR CUSTODIAN (Include Area Code) Primary: _____ Secondary: _____ | |
| 42B. E-MAIL ADDRESS OF PARENT, GUARDIAN, OR CUSTODIAN (If applicable) | |
| 43A. SIGNATURE OF: (Check one) <input type="checkbox"/> PARENT <input type="checkbox"/> GUARDIAN <input type="checkbox"/> CUSTODIAN SIGN HERE ► IN INK (DO NOT PRINT) | 43B. DATE SIGNED |

From: Wilkie, Robert L., Jr.
Sent: Sat, 21 Mar 2020 15:33:32 +0000
To: RLW
Subject: FW: [EXTERNAL] Subj: Pandemic
Attachments: Europa Resume 2015.doc

From: (b)(6)
Sent: Saturday, March 21, 2020 11:25:26 AM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.; (b)(6)@wh.gov
Subject: [EXTERNAL] Subj: Pandemic

I understand the difficulty our nation finds itself. I do not believe throwing money addresses the public's or market concerns. What is necessary is a comprehensive, cogent strategic plan deploying all the resources available to stem the tide of the corona-virus tsunami. Here is a suggestion:

1. Activate the National Disaster Medical System (with nearly 800+ VA CBOC's.) for this Emergency Medical Preparedness. DoD would take the lead. They have expertise in logistics, support and supply chain relationships. VA serves as backup with 800+ CBOC's available for testing, diagnostics and initial triage recommendation. The state, county and private sectors would be the third tier in this national safety net.
 2. POTUS by Executive Order provides Part B Medicare for all on a time limited basis until Congress can meet and vote. However, this would be Part Version 2; it would be for preventative care, testing, and diagnostic, and recommendation to safety net facilities if citizen is uninsured.
 3. POTUS advises that 50 million test kits will be ordered. Those with symptoms will be tested initially but eventually most if not all will be tested to provide accurate data enabling health care system to properly and accurately identify and treat anyone infected. Any test kits not used will be donated to other countries to help stem the spreading tide of infection.
 4. Vice President Pence and his team will provide protocols & template for triage teams in each county to mitigate, diminish, and eliminate current crisis concerns at local level. The state governors would oversee the networks developed for their counties.
 5. Use of VA staff, supplies, and facilities on non veterans would require a supplemental budget of \$100 Billion. DoD would have to submit its own budget to take on this task.
 6. Reach out to current and former (retirees) staff who have served as Health Care Facilities or Health Systems Specialists to return to service on a time limited basis to assist converting spaces to triage/clinical care and hotels into beds to meet code requirements.
- We can do this. I am volunteering my services wherever they are needed.

Respectfully

(b)(6)

1.

(b)(6)
(b)(6) **FL**
(b)(6)
410-489-(b)(6)

Experience: In my 33 year career in Department of Veterans Affairs I was a Health Care Specialist working in the Office of Construction at VA Central Office planning major construction projects (over \$10 M (million) from 1981 thru 1989; a project leader in the field (Cleveland, OH) planning and activating major projects from 1989 thru 1992; a Health Care Systems Specialist writing policy and protocols for developing major projects in Region 1 (Baltimore, MD) from 1992 thru 1996; and a Senior Budget Analyst reviewing major project applications for funding consideration and developing National Capital Asset Plan and many other duties.

Background: From 2009 to 2013 - I retired from James A. Haley VA Hospital, Tampa, Florida in 2013 where I was the Director of Corporate and Strategic Planning. This VA hospital employs almost 5,000FTE, has an annual budget of \$800M. The infrastructure is comprised of 1.2M square feet plus an additional 31 leases with an annual leased cost of \$9.1M. It was responsibility to maintain all leases, complete strategic planning for this facility as well as plan, develop, co-ordinate and execute all activation tasks for this facility. This involved full participation by the primary, specialty and nursing, clinical, section, and administrative chiefs who were stakeholders in the scope of the project including staff impacted by any relocation and/or backfill moves.

I arrived at James A. Haley Hospital in March 2009 after 29 years in VA Central Office (VACO) Washington. D.C. Majority of that history and experience is noted below. (In the 80's I worked in the Office of Construction. I had many significant construction projects over \$50M but I am most proud that I was the project leader and planner for the VA Replacement Medical Center in Detroit, MI (\$252M) which at the time was the largest construction contract ever awarded in the history of the VA.

1996-2009 –

1. I was the senior analyst in Capital Asset Policy, Planning, and Strategy Service (CAPPS) within the Office Asset Enterprise Management (OAEM). I was involved with developing policy, procedures, and protocol for capital assets to govern the acquisition, management and disposal of capital assets for VA's portfolio of capital assets

2. As a Senior Analyst one of my duties was to review the chapters developed by Cannon Inc. (contractors) and VACO staff to adopt DoD's Space and Equipment Planning Software II (SEPS II) for VA use nationwide. I reviewed submittals and made recommendations where necessary. My position required that I have a comprehensive knowledge of the Department's capital asset policies, for each category of asset, the capital programs, and how they function within each administration (VHA {healthcare}, VBA {benefits} and VCA [cemeteries]). I developed a large network of contacts within each administration to ensure that all information was distributed to the field and all were

working in concert to achieve the Department's strategic goals while complying with all necessary legislative mandates: GPRA, Clinger-Cohen, FASA, Executive Orders, OMB requirements and GAO recommendations. I have served as acting Director in CAPPs and have demonstrated my aptitude in planning, organizing, and directing the work of others.

3. I was the only analyst that participated at the Senior level in the major projects (over \$10 million), minor projects (under \$10 million), Non-Recurring Maintenance (NRM) projects, and the Community Based Outpatient Clinic (CBOC) review process. I had oversight responsibility for the latter three construction programs (Minor, NRM, and CBOC's). I successfully negotiated the review and approval of more than 662 CBOC's since this program was developed. In addition, I have reviewed and negotiated with VHA the development of a contract template for Community Based Inpatient Contracts (CBIC's) that should be ready for Secretary's approval. These programs and associated activities provide me with the unique perspective to interpret agency-wide policies and procedures and guidelines and prioritize their impact on asset programs because I can assess their interdependent linkages across all construction programs.

4. I was the sole representative from OEAM that serves on the Completion Item Review Board, the Major Construction Project Working Reserve Board, and I serve on Veteran Health Administration's (VHA) Capital Asset Screening Committee (Cte.) and VHA's Enhanced-Use Screening Cte.

5. I received a Special Contribution Award in FY 2005 for developing VA's Sustainment Model to project estimated budget needed to address maintenance and operations in the NRM Program for VA facilities. The model was adapted from DoD's Facilities Unit Pricing Guide and tailored to meet VA's medical programs including special emphasis medical programs such as SCI, Nursing Home, Domiciliary, etc. The model was then enhanced to incorporate specific features from NASA's model which identified unfunded needs based on the Facility Condition Assessment. This combination VA hybrid Sustainment Model resulted in significant increase in VA's NRM budget from \$350M to \$750M

6. In 2002 and 2003 I was involved with the Consolidated Mail-Out Pharmacy (CMOP) a \$3 Billion program and in 2003 was formally appointed to the Board of Directors. My contribution provided CMOP's with an understanding of the elements and cost factors and criteria needed to develop a comprehensive business plan and an Emergency Management Plan. An outside contractor was recommended who would evaluate criteria used for site selection and assess different funding mechanisms to support this program. Options evaluated were Enhanced-Use, public bonds, trusts, municipal/local bonds and other public-private ventures to minimize VA's cost. VHA determined that such a rigorous approach was not necessary at the time and any risks to the CMOPs due to weather or other unforeseen conditions could be supported and resolved within VHA.

7. During FY 2003 and 2004 I served as a point of contact for CARES and was involved with developing and evaluating instruments that were used to develop CARES Planning Initiatives. I participated in evaluation of the CARES Market Plans, reviewed the CARES Commission Report for potential impact on major construction program, and finally the Secretary's CARES decision. Subsequently, in FY 2004 I received a Certificate of

Appreciation from VHA in recognition of my contribution as a member of the Technical Evaluation Team that reviewed, evaluated and ranked contractor proposals for the CARES Re-Use Studies contract.

8. Also, during this time period in FY 2003 and 2004 I served on the Federal Asset Disposal Task Force sponsored by GSA to establish a federal-wide protocol for the auctioning of capital assets.

9. In addition, between 2003 and 2009 I served as one of the points of contact (POC) in our office (CAPPS) for VA/DoD collaborative ventures as part of Construction Planning Council (CPC). (I will expand on this collateral duty later in my resume.) The work group accepted my recommendation for the structure and representation of staff from the field and headquarters establishing a Core Group to review all potential and proposed VA/DoD collaborative efforts in the major and minor construction programs.

10. I was a principal architect in the development of VA's capital investment process in 1997. I was involved with this endeavor from its inception thru 2009. I reviewed capital asset proposals and OMB 300 applications (approximately 60 proposals annually), provided validity assessments and mitigation plans for each project and assisted in formulating our annual 'Lessons Learned' as a result of each annual formulation cycle. I have played a role reviewing, coordinating, or validating proposals during each formulation phase since we developed the methodology and capital investment process in 1998. As part of the process I was responsible developing a scenario to use "Optimization" methodology to ensure VA received the best return on the investment.

In 1998 I had sole responsibility to craft the VA's Capital Investment Guide. Subsequently in 1999 and 2000 I participated in the development of the Capital Asset Plan (CAP). Then due to CARES the CAP was suspended until that process was completed. In May 2004 the Secretary made his decision that allowing for the development of the CAP and the Asset Management Plan, in which I participated. I have been involved every year in the updating the Capital Investment Guide either as a contributor or coordinating the involvement and participation of others. Since I was the primary author for the first two editions of the Capital Investment Guide it has been institutionalized and updated annually by other members of our office. Additionally, I am the lead person when changes to definitions or criteria are being considered for the capital investment process. In FY 2005 my updates for FY 2008 VA's Capital Application included developing and incorporating several tables for capturing and analyzing projected workload for specialty clinics and identifying specialty clinic hours related to waiting times. I also successfully developed and integrated a table that identified the project scope and related clinics or nursing units and their existing square feet, projected square feet, existing vacant space, and projected use of vacant space. Another enhancement I added identified the method of accomplishment for space needed to complete the scope of the project: new space, renovated space, and use of vacant space. I also successfully integrated the Facility Condition Index into the OMB 300 application without request or direction by management. During this development phase I chaired a VA work group, which had representatives from each administration in headquarters and from the field. The group successfully developed a Cost Effectiveness Analysis (CEA) template that was adopted by the Department establishing a system-wide

protocol for developing financial estimates for each alternative in a project application. The CEA identifies the least costly alternative and highlights project related risk factors for the Department. This effort set financial policy by using OMB-A94 for inflation and discount factors and provided a glossary for standardizing language for both public and private ventures. My duties continued to evolve and expand. I was a primary architect in establishing the current capital investment process. I leveraged my expertise from previous positions to develop and refine the capital investment process by capturing quantitative and qualitative data into a robust application that incorporated alternatives, financial analysis, cost/benefit and risk analyses. I was 'core member' of the team that developed and presented a vision and a blueprint for streamlining the capital asset process and anchoring all capital investment decision to the strategic goals

I also proposed introducing digital dashboards for executives at that time, however, we did not have the enterprise infrastructure in place to capture relevant data to produce the dashboards. I have also proposed implementing 'business scorecard' approach fashioned after the Harvard business model. These innovations could not have been integrated into our capital process without comprehensive knowledge of the complex issues at stake for each administration, impact on funding thresholds and budget formulation and execution processes and accompanying milestones. In 2002 I recommended that VA adopt the "Monte Carlo" Risk Analysis methodology. Later at OMB's direction in 2007 the VA and all federal agencies adopted dashboards and scorecard methodologies.

11. I 2000 had the opportunity to serve as Special Assistant to the Acting Secretary of the VA, Mr. Hershel Gober, for four months. Part of my duties included preparing special correspondence, taking meeting notes, crafting white papers, developing reports on the SES program in the VA, and editing speeches for the Acting Secretary. As Special Assistant to the Acting Secretary, I was involved with meeting Senior VA officials on a daily basis and accompanied Mr. Gober on site visits and National Veterans Service Conventions, e.g. VFW & American Legion. In addition the following were accomplished:

- Mr. Gober had requested a TV broadcast studio should be constructed in VACO. The project floundered for 18 months. He asked me to intercede to determine if I was up to the challenge and if I could complete the task. Project was completed in 3 months and Mr. Gober gave the first broadcast from the studio before he left office in January 2000.
- I observed the Secretary and learned how to interact and establish effective working relationships with VA political appointees, executive staff, and external stakeholders. He reached out to all people with varying educational levels, backgrounds, and divergent opinions and priorities in order to arrive at consensus in areas that have far reaching or agency-wide implications.
- I participated in executive management meetings, as well as, one-to-one meetings with the Secretary and Assistant Secretaries, observing and taking notes for the record. I also participated in Secretary's meetings with Veteran Service Organization Commanders, congressional representatives and White House staff.

- I gave a presentation to the Minister of Patriots from South Korea on the VA's Capital Investment Process and attended a closed meeting with the Ambassador of Bosnia, the Prime Minister and his interpreter.
- I was responsible for some of the advance planning and protocols for the Secretary's trips. I accompanied him to Hawaii for the 50th Anniversary in Remembering Veterans of the Korean War and to San Juan, PR for the National State Veterans Home Commanders Conference.

12. I served as primary contact with DoD on the Capital Budget Workgroup. The Capital Budget Workgroup was established under the CAPC, to review each department's overall capital asset planning process in order to identify opportunities and challenges to capital collaborations for FY 2005 through 2009 as well as establishing overarching funding principles applicable to joint collaborations. I am familiar with issues outside the department such as VA/DoD VHA Sharing Directive and the VA/DoD Joint Executive Council Structure (PL 107-314).

There have been many efforts by Congress and the Executive Branch to target increasing cooperation and sharing between VA and the Department of Defense (DoD) in order to improve the efficiency and cost-effectiveness of health care delivery for beneficiaries. (In my capacity I have attended Congressional Hearings before the Sub-Committee on Military Quality of Life and Veterans Affairs of the House Appropriations Committee and the Sub-Committee on Military Construction and Veterans Affairs, and related Agencies of the Appropriations Committee on Fiscal Year 2007 Base and Realignment and Closure Budget.)

President George W. Bush established a task force to identify the forces that present challenges to cooperation. The President's Task Force to Improve Health Care for Our Nation's Veterans was established by Executive Order 13214 on May 28, 2001. To formalize this goal and institutionalize collaboration between Departments, the President made "Coordination of Veterans Affairs and Defense Programs and Systems" one of 14 management initiatives in the President's Management Agenda.

In pursuit of the President's Management Agenda and in concert with the Task Force's organizing principles, the VA/DoD Capital Asset Planning and Coordination (CAPC) Steering Committee was created under the VA/DoD Joint Executive Council (JEC). The CAPC Steering Committee was established to provide formalized structure to facilitate cooperation and collaboration in achieving an integrated approach to capital coordination that considers both short-term and long-term strategic capital issues and is mutually beneficial to both departments. The primary focus of this group is to provide the oversight necessary to ensure collaborative opportunities for joint capital asset planning are maximized by serving as the clearinghouse for the final review and approval of all joint capital asset initiatives. The CAPC was renamed as the Construction Planning Council (CPC) late in FY 04 to more accurately reflect the task of the council. The CPC is comprised of individuals with comprehensive knowledge of relevant policy issues

within their respective agencies with regard to capital asset planning, investment, and management.

13. My duties on the CPC included reviewing the VA/DOD Joint Strategic Plan, as well as, DoD's 1391 (project applications) and compare them to our OMB 300 applications to evaluate opportunity for collaborative ventures. In November 2004 the Joint Strategic Plan proposed a revision for FY 2005 for Goal 5 – Efficiency of Operations. This goal targets the improvement of management of capital assets, procurement, logistics, financial transactions, and human resources. The main objective of this goal is VA/DoD CPC will identify areas for collaborative construction and pilot a “core group” process to develop a collaborative opportunity through formulation. I developed the charter for the ‘Core Group’ (CG) that was reviewed and approved by both departments.

A ‘core group’ was established as a committee under the aegis of the CPC and is co-chaired by DoD's Director of Portfolio Planning and Management and VA's Office of Asset Enterprise Management. The CG is comprised of permanent individuals from the Department and headquarters levels and variable members from the local and regional levels who would participate depending upon the location of the project to accomplish the following: identify sites; identify collaborative leasing opportunities; develop funding opportunities; create a master database of capital opportunities.

14. I also developed White Papers for ‘Financing Options between the departments and wrote the primer for ‘Funding Principles for VA/DoD’ that was in review process (when I left Washington for a new position in Tampa). Several improvements initiated by our workgroup were updating the zip codes, health care mission and distances between VA/DOD facilities. I am working with TMA staff to develop a “Call Letter” that will provide guidelines for data (beds/workload/ FTE/etc.) needed to initiate a joint venture major construction project. VA/DoD has recommended 5 sites for collaboration that address each of the three funding principles scenarios. The work group accepted my suggestion for the structure and representation of staff from the field and headquarters establishing a Core Group to review all potential and proposed VA/DoD collaborative efforts in the major and minor construction programs.

15. In 2006 I was invited several times to address DoD/TMA staff to brief them about VA's Capital Investment Methodology, our use of Analytical Hierarchy Process (AHP), the construction of our Decision Model, and web based OMB 300 application. Subsequently, I was invited to return and to present again to DoD senior leadership and Surgeon Generals from each military branch were in attendance. I was advised I ‘hit a home run’ and DoD adopted our investment process and methodology. I was invited back to assist them in development of their model and application. I was continually involved editing/reviewing the development/writing of DoD's Capital Investment Guide and tailoring VA's investment templates to meet DoD's nomenclature and budget needs. .

16. In March 2007, I was detailed by Assistant Secretary of Management (04) to serve on Secretary Nicholson's Global War On Terrorism Task Force Heroes that was established by Executive Order by POTUS and chaired by Admiral Dunne. This Task Force completed the initial groundwork for the Dole/Shalala Commission. We developed

our plan and recommendations in 90 days and then had to implement those recommendations in 90 days. The only constraint placed on us in developing recommendations was that we could not ask for additional funding or changes to legislation. I chaired the Education Group. We were successful in meeting all of our objectives.

From: Wilkie, Robert L., Jr.
Sent: Sat, 21 Mar 2020 21:52:02 +0000
To: RLW
Subject: FW: [EXTERNAL] Fwd: Important Series: "Health at Home" OZONE

From: (b)(6)
Sent: Saturday, March 21, 2020 5:50:32 PM (UTC-05:00) Eastern Time (US & Canada)
To: (b)(6) Ramoni, Rachel; Wilkie, Robert L., Jr.; Management
Subject: [EXTERNAL] Fwd: Important Series: "Health at Home" OZONE

Dear Drs (b)(6) & Rachel and Secretary Bob
By sharing this all w/ the US Veterans Administration...and you agree,
please take this opportunity to share same w/ the C D C?
My very best & GOOD LUCK at the VA

(b)(6) 617 899-(b)(6)

----- Forwarded message -----

From: (b)(6)@gmail.com>
Date: Sat, Mar 21, 2020 at 10:03 AM
Subject: Re: Important Series: "Health at Home" OZONE
To: (b)(6)@sophiahi.com>

Dear Dr. (b)(6)

We all hold you at a very high level of respect...do not understand why you at the Sophia health Institute do not provide a ClO2 kit. it usually sells for \$25 - \$50 for the 2-part containers. Ozone (O3) has a voltage of 252mv and can only take one (1) electron from a pathogen, H2O2 has a voltage of 129mv and can take two (2) electrons from a pathogen. ClO2* has a (safe) voltage of 95mv and can take five (5) electrons from a pathogen..

*Healing the Symptoms of Autism by Kerry Rivera, et al

I keep some made-up stored in my refrigerator (diluted) in a pint jar of H2O. When I feel I've contracted a bug,

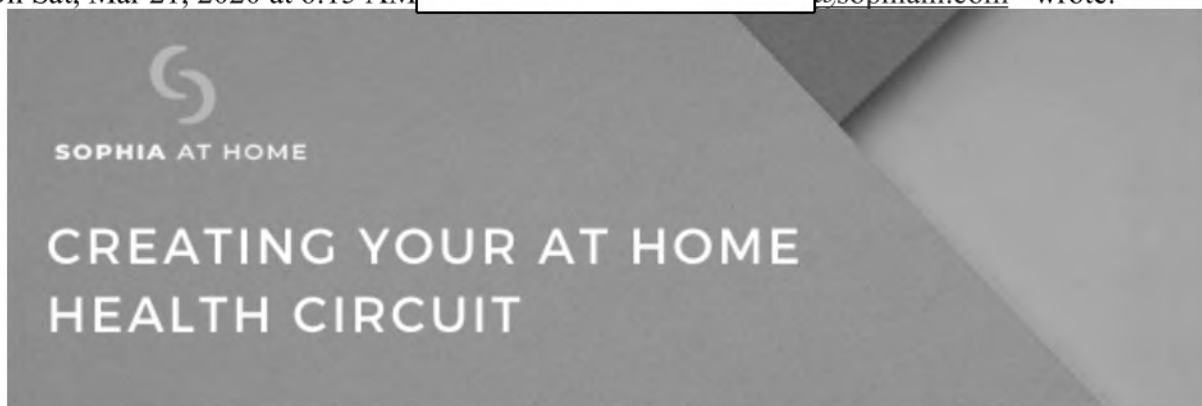
I drink 2-3 oz, start sweating in 30-minutes and after a 3-hour nap, the bug is gone, gone, gone!

PLEASE BE AWARE THAT DUPONT SELLS ClO2 AS A GAS BY THE THOUSANDS OF TONS ANNUALLY ALLOVER THE WORLD FOR WATER TREATMENT.

My warmest regards,

(b)(6) 617 899-(b)(6)

On Sat, Mar 21, 2020 at 6:15 AM (b)(6)@sophiahi.com> wrote:



Dear (b)(6)

We know this is a frightening time, but make no mistake, you are never powerless over your health journey.

To support you, we are launching a powerful new series by email - and today we will cover what you need to know about OZONE THERAPY.

But first, an important overview. In the wake of the fast-changing landscape and growing need to stay home (and potentially even “shelter in place” for the foreseeable future), we are devoting ourselves to supporting our patients and communities in the most accessible ways possible.

Over the next few weeks, we will offer a **powerful educational email series** focused on the tools and protocols needed to create your **AT HOME HEALTH CIRCUIT**.

Our team will be sharing practices, protocols and products that you can use in the convenience of your home and day-to-day life. These are some of the things the professionals at Sophia Clinic and I personally employ in our lives, to protect our own families, as well as what we share with our clinic patients - and now, with you.

Some of these suggestions will be easy-to-implement DIY practices, and some may involve larger commitments or investments. As always, you are in charge of

your situation and what feels right for your health journey.

As an aside, we are aware that health-related products and supplements are beginning to sell out and go on backorder, and we are working, on your behalf, to secure the products we think you may need.

Note: We will highlight those products we have been able to secure, as the need arises, but know that we may have access to very limited quantities, so please do not delay ordering a supplement or product you believe to be important for you or your family.

THE CIRCUIT: OZONE THERAPY

Ozone therapy has been proven to balance immune function, fight diseases, and increase energy.

AND it is one of the most powerful home health treatments ever available. It also has over 100 years of medical history and over 2,000 published medical studies.

It is used by over 50,000 doctors worldwide, on a daily basis, including our team at the Sophia Health Institute.

Ozone therapy entails using a medical ozone generator to generate medical ozone gas, which is then administered via the rectum and the ears, by drinking ozone water, and more.

This is an extremely versatile therapy because it fundamentally supports the body to work more effectively and works with the core mechanisms of the body and disease. Whereas a drug usually goes into the body to turn something on, or off.

Ozone therapy is commonly used for viral infections, bacterial infections, Lyme, cancer, autoimmune disease, and preventative care/general wellness.

It works by stimulating mild oxidative stress in the body, triggering the NRF-2 pathway. This is the same pathway that is activated during exercise and fasting. It stimulates the body into a health and optimization mode that helps to eradicate

disease and improve bodily functions on a cellular level.

If you have the means to make the investment, ozone therapy should be everyone's first investment in their Home Health Circuit.

(If this is beyond your means, don't worry - "Health at Home" will be updating you with more important ideas and information several times a week. Be sure to open every email.)

[CLICK HERE TO BUY YOUR SOPHIA CORONA OZONE KIT](#)

Use code "SOPHIA" for 10% off your order.

Why is OZONE an especially important tool in the current environment?

1. It's a powerful anti-viral and infection treatment.
2. It can be used for chronic disease, preventative care, ear infections, common cold, skin infections, and much more.
3. It's a great investment for any home, because it may remove the need for antibiotics.
4. The time investment is minimal, and treatments take less than 5 minutes, 3x per week.

The three key treatments to Ozone Therapy at home are rectal insufflation, ear insufflation, and ozone water.

The kit we have secured for our community includes all of the equipment necessary for these key treatments.

We are thrilled we have been able to secure this tool, in limited quantities, for our community.

Wishing you good health,

Dr. Christine Schaffner

PS: You can easily employ ozone therapy to significantly improve your immune system, encourage homeostasis, and decrease the likelihood of disease.

[Unsubscribe](#)

Sophia Health Institute 18106 140th Ave NE Suite 102 Woodinville, Washington 98072 United States

From: Wilkie, Robert L., Jr.
Sent: Sat, 21 Mar 2020 22:39:15 +0000
To: RLW
Subject: FW: Automatic reply: Automatic reply: [EXTERNAL] Fw: VA FORM 28-0957

From: (b)(6)
Sent: Saturday, March 21, 2020 6:36:07 PM (UTC-05:00) Eastern Time (US & Canada)
To: (b)(6)@snhu.edu
Cc: Wilkie, Robert L., Jr.
Subject: Fw: Automatic reply: Automatic reply: [EXTERNAL] Fw: VA FORM 28-0957

Because of the CORONA virus situation i am not able to get my education CH 31 benefits extension approved. Can i get some support from someone? I have already lost a semester of not being able to register for classes. The next one is scheduled to start April 6. Please advise...

V/r

(b)(6)

----- Forwarded Message -----

From: (b)(6), VBAMPI (b)(6)@va.gov>
To: (b)(6)@yahoo.com>
Sent: Saturday, March 21, 2020, 5:27:34 PM CDT
Subject: Automatic reply: Automatic reply: [EXTERNAL] Fw: VA FORM 28-0957

Hello,

Good morning.

Thank you for your email.

Thank you for extending your patience and understanding. I am currently assisting 95 veterans, who are still waiting for initial appointment and comprehensive evaluation of their application for vocational rehabilitation and employment services.

Please allow 2 to 3 days for me to address your concerns regarding your Training and Employment Needs.

For immediate concerns, kindly send a follow-up email.

Thank you for understanding.

Have a nice day.

(b)(6) RN RPsy

Certified Vocational Rehabilitation Counselor

From: (b)(6) EOP/OVP
Sent: Sat, 21 Mar 2020 22:53:58 +0000
To: Stone, Richard A., MD; Lawrence, Paul R., VBAVACO
Subject: FW: [EXTERNAL] White House Coronavirus Task Force Call
Attachments: White House Coronavirus Task Force Agenda 3.22.20.docx
Importance: High

Task force call is at 3 pm on Sunday if you are interested.

Sent with BlackBerry Work
(www.blackberry.com)

From: (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>
Date: Saturday, Mar 21, 2020, 6:52 PM
To: (b)(6)@mail.house.gov, (b)(6)@mail.house.gov, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@HHS.GOV, (b)(6)@HHS.GOV, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, Kudlow, Larry A. EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@cdc.gov <(b)(6)@cdc.gov>, (b)(6)@niaid.nih.gov <(b)(6)@niaid.nih.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6)@state.gov <(b)(6)@state.gov>, (b)(6)@fda.hhs.gov <(b)(6)@fda.hhs.gov>, (b)(6)@hq.dhs.gov <(b)(6)@hq.dhs.gov>, Birx, Deborah L. EOP/NSC <(b)(6)@nsc.eop.gov>, (b)(6)@cms.hhs.gov <(b)(6)@cms.hhs.gov>, RLW <(b)(6)@va.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OMB <(b)(6)@omb.eop.gov>, Miller, Katie R. EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/NSC <(b)(6)@nsc.eop.gov>, (b)(6) (OS/OASH) <(b)(6)@hhs.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, Miller, Stephen EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@fema.dhs.gov <(b)(6)@fema.dhs.gov>, (b)(6) HHS <(b)(6)@hhs.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6) EOP/NSC <(b)(6)@nsc.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, Kushner, Jared C. EOP/WHO <(b)(6)@who.eop.gov>, Hicks, Hope C. EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6)@dot.gov <(b)(6)@dot.gov>, Kate@mail.house.gov <Kate@mail.house.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6)@hud.gov <(b)(6)@hud.gov>, (b)(6)@hud.gov <(b)(6)@hud.gov>, (b)(6)@hud.gov <(b)(6)@hud.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)

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EOP/WHO <(b)(6)> @who.eop.gov>, (b)(6) (HHS/OASH) <(b)(6)> @hhs.gov>,
(b)(6) EOP/WHO <(b)(6)> @who.eop.gov>, (b)(6) EOP/WHO
(b)(6) @who.eop.gov>

Subject: [EXTERNAL] White House Coronavirus Task Force Call

Good evening,

There will be a **White House Coronavirus Task Force Call** on **Sunday, March 22 at 3:00pm EST**. Preliminary agenda attached.

A registration link will be provided to essential staff and assistants to principals shortly.

Please note: Only principals should register for tomorrow's call. If you have questions regarding your participation, please do not hesitate to reach out.

Thank you,

(b)(6)

Operations Coordinator, White House Coronavirus Task Force
Executive Assistant to the Chief of Staff

The Office of the Vice President
(202) 881-(b)(6)



OFFICE OF THE VICE PRESIDENT
WASHINGTON

WHITE HOUSE CORONAVIRUS TASK FORCE AGENDA

Sunday, March 22, 2020
3:00pm EST

I. **Opening Remarks** – (b)(5)

II. **Data Update** – (b)(5)

- (b)(5)

III. **Testing Update** – (b)(5)

IV. **Supplies Update** – S (b)(5)

- (b)(5)
-

V. **Executive Orders:** (b)(5)

(b)(5)

VI. **New York Stockpile Distribution** – (b)(5)

VII. **Concluding Remarks** – (b)(5)

From: (b)(6) EOP/OVP
Sent: Sat, 21 Mar 2020 22:54:35 +0000
To: (b)(6)
Subject: FW: [EXTERNAL] White House Coronavirus Task Force Call
Attachments: White House Coronavirus Task Force Agenda 3.22.20.docx
Importance: High

Please have them pick me up at 2:30 on Sunday.

Sent with BlackBerry Work
(www.blackberry.com)

From: (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>
Date: Saturday, Mar 21, 2020, 6:52 PM
To: (b)(6)@mail.house.gov, (b)(6)@mail.house.gov, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@HHS.GOV <(b)(6)@HHS.GOV>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, Kudlow, Larry A. EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@cdc.gov <(b)(6)@cdc.gov>, (b)(6)@niaid.nih.gov <(b)(6)@niaid.nih.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6)@state.gov <(b)(6)@state.gov>, (b)(6)@fda.hhs.gov <(b)(6)@fda.hhs.gov>, (b)(6)@hq.dhs.gov <(b)(6)@hq.dhs.gov>, Birx, Deborah L. EOP/NSC <(b)(6)@nsc.eop.gov>, (b)(6)@cms.hhs.gov <(b)(6)@cms.hhs.gov>, RLW <(b)(6)@va.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OMB <(b)(6)@omb.eop.gov>, Miller, Katie R. EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/NSC <(b)(6)@nsc.eop.gov>, (b)(6) (OS/OASH) <(b)(6)@hhs.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, Miller, Stephen EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@fema.dhs.gov <(b)(6)@fema.dhs.gov>, (b)(6) (HHS) <(b)(6)@hhs.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6) A. EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) IV <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6) EOP/NSC <(b)(6)@nsc.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, Kushner, Jared C. EOP/WHO <(b)(6)@who.eop.gov>, Hicks, Hope C. EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/OVP <(b)(6)@ovp.eop.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>, (b)(6)@dot.gov <(b)(6)@dot.gov>, Kate@mail.house.gov <Kate@mail.house.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) D. EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6)@treasury.gov <(b)(6)@treasury.gov>, (b)(6)@hud.gov <(b)(6)@hud.gov>, (b)(6)@hud.gov <(b)(6)@hud.gov>, (b)(6)@hud.gov <(b)(6)@hud.gov>, (b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)

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Pamela <(b)(6)@va.gov>, (b)(6)@va.gov>, (b)(6)@va.gov>, (b)(6)@va.gov>,
(b)(6)@va.gov>, (b)(6) EOP/NSC <(b)(6)@nsc.eop.gov>,
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EOP/WHO <(b)(6)@who.eop.gov>, (b)(6)@sd.mil
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(b)(6) EOP/WHO <(b)(6)@who.eop.gov>, DL WHO COMMS Speechwriters
(b)(6)@whmo.mil>, (b)(6)@hhs.gov
<(b)(6)@hhs.gov>, (b)(6)@hhs.gov <(b)(6)@hhs.gov>,
(b)(6)@dot.gov <(b)(6)@dot.gov>, (b)(6)@dot.gov <(b)(6)@dot.gov>,
(b)(6)@fema.dhs.gov <(b)(6)@fema.dhs.gov>, (b)(6) EOP/WHO
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EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) HHS/OASH <(b)(6)@hhs.gov>,
(b)(6) EOP/WHO <(b)(6)@who.eop.gov>, (b)(6) EOP/WHO
<(b)(6)@who.eop.gov>

Subject: [EXTERNAL] White House Coronavirus Task Force Call

Good evening,

There will be a **White House Coronavirus Task Force Call on Sunday, March 22 at 3:00pm EST.** Preliminary agenda attached.

A registration link will be provided to essential staff and assistants to principals shortly.

Please note: Only principals should register for tomorrow's call. If you have questions regarding your participation, please do not hesitate to reach out.

Thank you,

(b)(6)

Operations Coordinator, White House Coronavirus Task Force
Executive Assistant to the Chief of Staff

The Office of the Vice President
(202) 881-(b)(6)



OFFICE OF THE VICE PRESIDENT
WASHINGTON

WHITE HOUSE CORONAVIRUS TASK FORCE AGENDA

Sunday, March 22, 2020
3:00pm EST

I. **Opening Remarks** – (b)(5)

II. **Data Update** – (b)(5)

○ (b)(5)

III. **Testing Update** – (b)(5)

IV. **Supplies Update** – (b)(5)

○ (b)(5)

○

V. **Executive Orders:** (b)(5)

(b)(5)

VI. **New York Stockpile Distribution** – (b)(5)

VII. **Concluding Remarks** – (b)(5)

From: Wilkie, Robert L., Jr.
Sent: Sat, 21 Mar 2020 22:55:23 +0000
To: RLW
Subject: FW: [EXTERNAL] Your employees with Special Needs must be permitted to use their Sick Leave days to self-quarantine from COVID-19

From: (b)(6)
Sent: Saturday, March 21, 2020 6:54:27 PM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [EXTERNAL] Your employees with Special Needs must be permitted to use their Sick Leave days to self-quarantine from COVID-19

Dear Mr. Wilkie,

I am contacting you to ask you if you could find it in your heart to temporarily relax the VAs policy on use of Sick Leave and permit VA employees to use their accumulated Sick Leave days if they have a disability and have a letter from their doctor instructing them to self-quarantine during this COVID-19 pandemic. Could you please allow this for your non-critical, non-medically necessary personnel to protect them and everyone they come in contact with? Below is an email I sent to VP Mike Pence and his Coronavirus Team, to Governor Tom Wolf of PA and my local legislators asking them to implore you to do this.

My brother (b)(6) who has an Intellectual Disability, is very vulnerable to contracting COVID-19 because he serves food in the VA Canteen at your Veteran's Administration Hospital in the Oakland section of Pittsburgh, PA, involving face-to-face interaction with the public with no protection. He has been told that sick leave cannot be used until he gets sick, and even though his doctor has written a letter to the VA informing him that he recommends he self-quarantine, he has been told he must use his own hard-earned vacation days to self-quarantine because he is not yet sick. He has worked there 16 years and has never used even ONE sick day -- never called in sick, never late for work, ever. He has accumulated sick leave which he desperately needs to be permitted to use. He does not have enough Annual Leave to cover him through this pandemic. He needs to be able to use the Sick Days he has earned now more than ever. Will you please help my brother and all of your employees who have Special Needs so they, our most vulnerable, are protected?

Please do this to protect all of your loyal staff who are our nation's most vulnerable -- our citizens with special needs who cannot protect themselves.

I look forward to hearing from you.

Thank you so much for any consideration you can give to address this life/death pandemic situation for my 57 year-old brother, whom I care for in my home and love more than life itself I cannot lose him, Mr. Wilkie..

Gratefully,

(b)(6)

Dear Vice President Pence,

I desperately need your help for my younger brother, (b)(6), who works at the VA Hospital in the Oakland section of Pittsburgh, PA. He has worked in the

VA Hospital Canteen (cafeteria) for 15 years, serving food to Veterans, patients, doctors, nurses, and other personnel. This requires him to have direct, face-to-face contact with customers during this time of the COVID-19 pandemic, exposing him and the food he serves to any transmission of germs from customers as he serves them.

(b)(6) is 57 years old and is among our nation's most vulnerable. He is a friend of (b)(6) who has told us all about you and how she met you and President Trump and how much she likes you. I heard you speak on TV today saying this pandemic is "a threat to the most vulnerable among us." (b)(6) has an intellectual disability which does not give him the skills required to keep himself safe and the VA has not provided any protection for him. During his entire length of employment, he has had perfect attendance -- never called off sick, never been late for work, etc. - ever. Because of his flawless record, he has accumulated over 34 weeks of paid sick time that he is eligible to take if he is sick. The problem is that the VA will not permit him to use those days unless he is sick; and presently, he is not. By requiring him to work under these conditions until he does get sick, however, he could infect unknown numbers of people. We feel so betrayed that the organization he has given his loyalty to for 15 years will not allow him to use his hard-earned sick days when he needs them the most -- to voluntarily self-quarantine so he does not get sick and I can care for him and keep him safe.

Vice President Pence, would you please ask the VA to do the right thing and allow vulnerable workers like (b)(6) who are not in life-saving jobs to use their sick days to self-quarantine to protect themselves and not require them to be physically sick already (as long as a doctor writes a letter verifying their vulnerability), and that they be permitted to take the entire amount of sick days they have earned to protect themselves during times of a pandemic of these proportions.

I am a Senior Citizen (b)(6) lives with me and I take care of him. Every day that he is required to be doing his job exposes me when he comes home -- his clothing, shoes, coats, are all contaminated because he has to take two forms of public transportation to get to his job. Please protect me and my dear baby brother. I know you have a soft spot in your heart for all our nation's most vulnerable, like (b)(6). I was so encouraged when I heard you on TV today and got so excited that I had to write you to now because you are my only hope for my brother and all VA

employees like him. I look forward to hearing from you as to whether you might be able to help us.

Thank you for everything you are doing to keep us safe! We are so proud of the job you are doing and so thankful that you are our leader on this effort.

Gratefully,

(b)(6)

(b)(6) PA (b)(6)

From: (b)(6)
Sent: Sun, 22 Mar 2020 01:52:37 +0000
To: RLW
Subject: [EXTERNAL] Fwd: Senate closing in on deal on \$1.6T rescue package

(b)(6)

Begin forwarded message:

From: POLITICO Pro <politicoemail@politicopro.com>
Date: March 21, 2020 at 8:46:07 PM EDT
To: (b)(6)@riponsociety.org>
Subject: Senate closing in on deal on \$1.6T rescue package
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-775930271-1376319-333568@politicoemail.com>

Senate closing in on deal on \$1.6T rescue package

By Sarah Ferris, Marianne LeVine, John Bresnahan

03/21/2020 11:31 AM EDT

Senate Republicans and Democrats have yet to reach an overall deal on a massive economic rescue package in response to the coronavirus crisis — but the two sides are getting closer. And Senate GOP leaders said Saturday they will press ahead with drafting portions of the bill, which will cost at least \$1.6 trillion, according to three GOP sources.

Senate Majority Leader Mitch McConnell remains adamant about sticking to a Monday deadline to hold a final vote on the legislation, the most expensive economic rescue package in U.S. history. McConnell has set up a critical procedural vote for Sunday afternoon, and he will need Democratic support to continue moving forward.

The two sides continue to squabble over boosting paid leave for sick workers and those caring for infected family members — a major issue for Democrats — as well as what kind of financial help the federal government can provide to distressed industries, such as the major U.S. airlines. The White House and Senate Republicans want several hundred billion dollars for impacted industries, said officials involved in the talks.

But there was significant progress during Saturday's negotiations on boosting unemployment insurance payments, a major source of contention between GOP and Democratic leaders on Capitol Hill. Senate Republicans have agreed to boost those payments by \$250 billion, a major win for Democrats, said two sources familiar with the discussions. This will come on top of \$250

billion in direct payments from the IRS to individual Americans, which President Donald Trump, Treasury Secretary Steven Mnuchin and Senate Republicans have made their key priority.

And Senate GOP leaders and the White House conceded to a Democratic demand for tens of billions of dollars for hospitals and health-care providers as part of the rescue package. There also appears to be broad support for \$350 billion in loans to small and medium-sized businesses that have been decimated as the U.S. economy grinds to a jarring halt in the facing of the growing coronavirus outbreak.

“What [McConnell] has instructed his committees to do is to finish drafting legislation that reflects agreements reached so far, and where the chairmen and the majority believe Democrats could be in a position to support by the time the vote occurs,” said White House Legislative Affairs Director Eric Ueland, a key Trump administration official involved in the high-level talks. “It’s critically important that Congress be in a position to act for the American people and the American economy on Monday.”

McConnell was hopeful about the prospects for an agreement, telling reporters: “I think we’re clearly going to get there.”

“Basically, we know the general contours of what this is going to look like,” added Senate Majority Whip John Thune (R-S.D.), as he left a closed-door GOP luncheon earlier in the day. Now it’s just a question of plugging in some of the policy, and figuring out where the numbers are.”

“The Democrats are getting some of the things they’ve asked for,” said Thune, ticking off priorities like immediate relief to individuals, protections for health care workers, and shoring up small businesses. “They’re getting what they wanted on unemployment insurance.”

Senate Democrats have been tight-lipped about specific issues but generally said Republicans were making good-faith offers as they attempt to reach agreement.

“We’ve reached a point where the big issues — the really big important issues — are just interrelated, and we can make progress,” added Sen. Ron Wyden (D-Ore.), one of his party’s top negotiators on financial issues.

In a sign that negotiations are reaching a critical point, Speaker Nancy Pelosi spent part of Saturday flying back to D.C. Mnuchin spoke with Pelosi and Senate Minority Leader Chuck Schumer during the afternoon.

"We're making very good progress. I'm optimistic we can make a deal," Schumer said late Saturday afternoon.

McConnell had originally demanded an agreement be reached by Saturday afternoon.

Mnuchin declined to comment on the talks, but told reporters that he's also spoken with President Donald Trump and Vice President Mike Pence.

"Everybody's working very hard," Mnuchin said just before 4 p.m. on Saturday.

Senate Republicans tried to break the deadlock by delivering their latest concession to Democrats on one of the biggest remaining issues — \$250 billion more for unemployment insurance payments. The two sides huddled separately as they sought a way to incorporate the Democratic demands, such as longer-term benefits for furloughed workers.

"We have a good bipartisan agreement on enhanced unemployment compensations," said Finance Chairman Chuck Grassley (R-Iowa).

As negotiations moved forward, the size and scope of the package appeared to steadily increase. The price tag of the legislation is now expected to exceed \$1.3 trillion, acknowledged National Economic Council Director Larry Kudlow. The total size of the package, including loans from the federal government, would likely exceed 10 percent of GDP — roughly \$2 trillion, he said. That would include a payroll tax holiday for small businesses.

During a Senate GOP lunch, Republicans discussed an idea from the Trump administration for possible specific assistance for General Electric and Boeing, but several pushed back on it, including Sen. Ted Cruz (R-Texas), according to two sources familiar with the meeting.

Cruz later tweeted his opposition to "a special carve-out" for the two companies, adding, "Millions are losing jobs; we don't need bailouts or corporate welfare—those companies should participate in the same liquidity programs as everyone else."

Inside the Trump administration, there is a strong desire to help both Boeing and GE, a major contributor to the Boeing supply chain. Both companies employ tens of thousands of workers, and the administration wants to prevent any major loss of jobs at the iconic firms.

In addition to providing the companies money or loans directly through the "Phase 3" package, Mnuchin is also trying to ensure the legislation gives both Treasury and the Federal Reserve the flexibility to loan the two companies additional funds, according to three sources familiar with the Hill negotiations.

Another issue still under negotiation is the Democrats' call for a "State Stabilization Fund," which would assist state governments with looming revenue shortfalls during the pandemic.

Democrats are optimistic about their ask on aid to states. In a tweet, Sen. Chris Murphy (D-Conn.) said Saturday that Republicans are now negotiating on the terms and amount of funding.

The debate over expanding paid leave may be the toughest remaining point of conflict.

The Senate pushed through the House's "Phase 2" relief package earlier this week which included new paid sick leave provisions. While the Senate approved the measure in a 90-8 vote, McConnell had to convince his caucus to support it and vowed to address shortcomings in this new, third stimulus package.

The discussions come after Senate Republicans introduced a \$1 trillion measure Thursday to salvage the economy by providing assistance to individuals, small businesses and industries.

Under the GOP proposal, individuals and families would receive \$1,200 and \$2,400 in direct cash payments based on their income. But some Republicans, including Sens. [Josh Hawley](#) (Mo.) and [Mitt Romney](#) (Utah), complained the proposal's structure — as written — would penalize lower income Americans who do not have a taxable income. Republican lawmakers and aides say this has been resolved.

Nancy Cook contributed to this report.

To view online:

<https://subscriber.politicopro.com/budget-appropriations/article/2020/03/senate-begins-second-day-of-negotiations-on-massive-stimulus-1899551>

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From: (b)(6)
Sent: Sun, 22 Mar 2020 13:20:34 +0000
To: RLW
Subject: [EXTERNAL] Fwd: Short-term thinking plagues Trump's coronavirus response

(b)(6)

Begin forwarded message:

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 21, 2020 at 8:57:45 PM EDT
To: (b)(6)@riponsociety.org>
Subject: Short-term thinking plagues Trump's coronavirus response
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-775930271-1376319-333611@politicoemail.com>

Short-term thinking plagues Trump's coronavirus response

By Dan Diamond

03/21/2020 08:56 PM EDT

After months of minimizing the threat to the United States, President Donald Trump jumped feet-first into the coronavirus fight this week with vows of quick fixes to the testing problem, claims about potential cures, and efforts to rope in agencies that had inexplicably been excluded, like FEMA.

The show of action played well in the White House briefing room and with the public, but has had a different impact behind the scenes. Health-agency officials and outside advisers to the administration, speaking on the condition of anonymity, described a chaotic situation in which leaders rushed to address presidential requests that sometimes seem to come on a whim while losing focus on longer-term challenges.

Trump's drive to announce unfinished initiatives created a "need to make good on half-baked promises," said one senior official — who, like other Americans, learned about some initiatives only when the president announced them at the White House podium.

For instance, no one in the White House had devised a national strategy for obtaining and distributing the necessary supplies in the likely months-long fight against the pandemic that lies ahead, said three people with knowledge of the planning efforts. Those supply-planning efforts are only now underway.

“How is there not a national supply strategy yet?” asked one official involved in the effort, warning that the infamous shortage of coronavirus tests is set to be replicated with other shortages across the health system. “Hospitals are going to run out of basic commodities.”

The U.S. health system already has been plagued by shortages of test-kit chemicals, swabs and personal protective equipment for health workers, problems that are set to worsen as coronavirus case numbers rise and demand spikes. A government effort to obtain replacement test swabs required the U.S. military this week to airlift the specialized swabs from a factory located in coronavirus-stricken Italy.

Meanwhile, leaders in coronavirus hot-spots like Seattle and New York City have effectively abandoned efforts to conduct broad testing on residents, instead urging them to stay home given the shortages — an acknowledgment that efforts to contain coronavirus have failed and they need to prioritize limited supplies. Local officials also are making unusual crowdsourcing appeals.

“We need companies to be creative to supply the crucial gear our healthcare workers need. NY will pay a premium and offer funding,” New York Gov. Andrew Cuomo tweeted on Friday. “If you have any of these unused supplies, please email COVID19supplies@esd.ny.gov.”

A sympathetic HHS staffer compared Cuomo’s plea to an internet auction. “We’re facing a pandemic and the governor has to basically turn to eBay” for supplies, the staffer said.

Trump has worked to tamp down concerns about insufficient tests and supplies, saying that the flurry of federal, state and local efforts will be sufficient. “If California can get a mask sooner than we can get it for them, through all of the things we're able to do, we'll end up with a big over-supply,” the president said at a press conference on Saturday. “At some point this is going away.”

Spokespeople for the Trump administration defended its planning and coordination for the coronavirus outbreak. “We’ve been working since January with American manufacturers to prepare for responding to the outbreak and will continue to coordinate closely with private suppliers and our federal partners to ensure that resources are going where they’re needed,” an HHS spokesperson said.

The White House said that Trump’s leadership had sparked an “unprecedented collaboration” of government and private industry to curb the virus’ spread and ramp up the response. “The president has no higher priority than the health and safety of the American people and he is working around the clock to ensure we emerge from this crisis healthy, safe, and strong,” said spokesperson Judd Deere.

Inside the Trump administration, officials are continuing to sort out which teams are responsible for elements of coronavirus response, part of an ever-shifting patchwork of alliances and strategy, while working to manage the president’s unpredictable requests. Five officials said that Trump had grown appropriately concerned about the coronavirus outbreak after weeks of ignoring or playing down the threat, but that the administration is now rushing to solve issues that could have been addressed months ago, like obtaining the necessary supplies for the nation’s

emergency stockpile.

Officials also are sniping over whether to institute even more aggressive actions to prevent coronavirus transmission. Health officials are calling for stricter measures that would keep more Americans at home, for longer, but policy officials warn that the resulting economic damage could cause other, long-lasting harms.

FEMA this week took over responsibilities that had rested with HHS, the latest attempt to get a handle on the worsening outbreak.

“FEMA is now leading federal operations for #COVID19 on behalf of the White House,” administrator Pete Gaynor tweeted on Thursday night, as some projects like drive-through test sites shifted from the health department. The agency is also taking on a larger role handling supply and distribution issues, Gaynor and other officials said at Saturday’s briefing.

“The tendency is to think of FEMA as a disaster management agency,” said Craig Fugate, who ran FEMA during the Obama administration and said he had no knowledge of the Trump administration’s strategy. “It’s actually an all-hazards agency ... and FEMA could add structure, planning, location to the coronavirus response,” with its regional offices and staff with crisis-management experience.

Some officials and outside advisers have questioned why FEMA had not been given more authority earlier in the response given the agency’s operational expertise in responding to disasters. Two individuals said that HHS Secretary Alex Azar had focused on protecting his leadership role, which has shrunk as Vice President Mike Pence took over the broader response and deputies whom Azar had originally sidelined — like Medicare chief Seema Verma and Surgeon General Jerome Adams — have emerged as key figures in White House strategy.

But a person familiar with HHS strategy said that Azar had pushed “weeks ago” for FEMA to be involved. The hold-up was instead linked to the federal response’s rotating leadership — as Pence abruptly took over for Azar at the end of February — and administration worries that states would be further confused over who was in charge.

“Secretary Azar and HHS have been and continue to be wholly supportive of a whole-of-government approach and in particular the important role FEMA is playing in coordinating the federal government’s response to Covid-19,” an HHS spokesperson said.

Meanwhile, a SWAT team of government officials and outside technocrats, backed by White House senior adviser Jared Kushner, spent the week working around-the-clock to deliver the drive-through testing sites that Trump publicly promised, POLITICO first reported.

But the focus on drive-through testing also creates a new problem — draining limited supplies and other resources that could be used for high-priority patients in hospitals.

“It’s all short-term thinking right now,” said one official involved in the response.

“They’re desperate to expand testing — which is a good idea — but I don’t know whether the president, the vice president and others at the top understand the trade-offs,” added an adviser to

the effort. “It feels like each of these problems is a mini-crisis being run by a mini-team in the government.”

Trump’s own involvement has caused additional headaches. Health department officials were confused on Wednesday after Trump announced that an “exciting FDA announcement” was on the way — particularly because FDA officials had yet to greenlight new drugs that Trump sought to fight the virus, The Wall Street Journal reported.

While Trump did hold a Thursday press conference with FDA Commissioner Steve Hahn and other officials, the event largely rehashed existing policies and work that had already been announced. Trump on Friday also repeatedly made claims about an unproven coronavirus treatment, prompting infectious-disease scientist Anthony Fauci to try and walk back the claims from the White House podium.

Meanwhile, the president has repeatedly touted unfinished projects, like announcing on March 13 a Google website that he said would help coordinate testing. But the actual site, which rolled out a week later, is instead a collection of information and links. Trump on Friday also claimed that General Motors has “openly stated” it would produce medical supplies. But GM has not publicly committed to producing more supplies, although the company is working with ventilator specialist Ventec to boost its production, according to a joint statement rushed out on Friday after Trump’s remarks.

"All options are on the table on how GM can help Ventec build more ventilators," a GM spokesperson said.

The chaotic response also has trickled down to individual hospitals, clinics and doctors, which have struggled to get answers on supply chains and fought to protect their equipment.

Sen. Bill Cassidy’s office reached out to the White House on Wednesday after learning that University Medical Center in Louisiana was informed that a new lab-testing machine, due to arrive on Monday, had instead been requisitioned by government officials for a “higher priority” coronavirus situation.

“We thought the machine was a high priority in Louisiana given the fast rate that things were spreading,” said a spokesperson for Cassidy’s office, noting that the state has become a hotspot for coronavirus transmission. The White House later assured Cassidy’s office that the machine would go to Louisiana next week, as originally intended.

Meanwhile, the Trump administration has spent weeks competing with states and hospitals to obtain medical supplies and quickly build up national reserves. “Every single governor across the country is looking for the exact same thing,” FEMA’s Gaynor said at Saturday’s White House press briefing, responding to questions about shortages.

Some experts said the president would be better served by developing a national strategy to allocate limited resources to the neediest areas while obtaining new ones, say experts, noting that dozens of individual components in the health system are at risk of being quickly diminished in the initial crush of cases — from the intricate chemicals needed for tests to the basic supplies that

could've been rapidly produced months ago.

“We’re seeing a run on swabs,” said a former official, arguing that the Trump administration should have anticipated the worldwide demand for the specialized, low-cost swabs needed to do the testing. “How on Earth did we let this happen?”

Tom Inglesby, director of the Johns Hopkins Center for Health Security, listed off the supply shortages that already are plaguing hospitals.

“They say they don’t have reagents for the diagnostic kits, they don’t have swabs for the kits, they don’t have the N95 masks, they’re running out of gowns and gloves,” said Inglesby, who’s called on the White House to overhaul its approach and assign specialists, such as the Pentagon’s Defense Logistics Agency, to solve the supply-chain problems.

“I don’t think we should see these as spot shortages that will soon be resolved with significant effort,” Inglesby added. “We will be using large amounts of these supplies for a long time. Covid will be with us for a long time — we need a long-term solution.”

Meanwhile, Trump on Saturday was asked about “the plan” to contain coronavirus as the nation enters day 6 of the White House’s 15-day campaign to slow the virus’ spread, and specifically whether additional measures needed to be taken.

The president declined to detail next steps, saying only that leaders would know more next week.

“We’ll have to see what the result is,” Trump said.

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From: Wilkie, Robert L., Jr.
Sent: Mon, 23 Mar 2020 11:30:24 +0000
To: RLW
Subject: FW: New Senate cloture-vote on \$1.6T Economic Stimulus this AM. Trump press conferences, (Friday, Saturday, Sunday). Major "surprises" in ~\$1.6T Senate "CARES" Bill. Strong USD(A&S) Lord actions to protect Industry. Boeing suspends \$4.6B dividend.

From: (b)(6)
Sent: Monday, March 23, 2020 7:29:38 AM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [EXTERNAL] New Senate cloture-vote on \$1.6T Economic Stimulus this AM. Trump press conferences, (Friday, Saturday, Sunday). Major "surprises" in ~\$1.6T Senate "CARES" Bill. Strong USD(A&S) Lord actions to protect Industry. Boeing suspends \$4.6B dividend.

Secretary Wilkie:



1. Senate cloture-vote on ~\$1.6T Economic Stimulus package failed on 47:47 vote, Sunday night, (60 votes required), (with House now drafting its own competing Bill); but Senate will re-vote at 9:45AM today, with stock markets open.

2a. Sunday Trump press conference on China Virus, (White House, March 22, 2020): Only ~one in ten Americans, that have symptoms, actually test positive for the virus. [~254K people tested so far, with ~30K confirmed US infections, (~390 deaths)] The US is at-war. Help the worker & protect companies, to protect the US Economy. Projecting that US Economy will spring back in late 2020, "because of pent-up demand".

- NY, CA, WA will receive additional National Guard troops, (under State Governor Title 32 authority), (not Federalized). FEMA will fund 100% of cost. State Governors are in-command, with FEMA paying-the-bills.
- Peter Navarro: White House is currently-using DPA as "quiet-leverage" with industry, because CEOs are already-volunteering. White House will use DPA to cut internal government red-tape, and to commandeer any goods from "production-hoarders".
- Boeing: "We have to be able to work with Boeing. Boeing was a great company, and will be a great company again, I think shortly...I don't want stock buy-backs..."

2b. Saturday Trump press conference on China virus, (White House, March 21, 2020): ["Win the war, with as few lives lost as possible"] [~195K diagnostic tests conducted; 19,343 have tested positive] China concealed that the virus is three times more contagious, and ten times more deadly, than the flu.

This is a government-imposed shutdown of the entire US Economy. This is not a corporate “bail-out”. Must inject liquidity into all aspects of the economy, while making workers whole. [~40% of total workforce is small business. If ~50% of those workers are let go, then worst-case unemployment could possibly be ~20%]

House & Senate should vote on ~\$1.6T Economic Stimulus package on Monday, March 23, 2020. US must pay people not-to-work, to kill the virus. Companies must be protected, workers must be protected, to preserve current economic capacity, for explosive-recovery, as soon as virus is killed off.

No corporate share repurchases or executive compensation raises, if you accept federal loans. Money can only be used to keep workers, hire workers, and build facilities.

2c. Friday Trump press conference on China virus, (White House, March 20, 2020): Mortality-rate is ~two-times higher in males, than females. US would look like Italy now, if early China travel-ban had not been implemented. China is in full-scale disinformation campaign.

In response to Q&A on ~\$60B Boeing loan request, Trump supports formal prohibition against any corporate share repurchases, (because loans are for retaining workers, hiring workers, and building facilities).

Trump has already-placed an order for “millions-of-units” of Chloroquine, (traditional malaria & arthritis drug), because of anecdotal success stories as a therapeutic, (to speed recovery of infected). [“What the hell do we have to lose?”]

3. Treasury Sec. Steve Mnuchin, (Fox News Sunday, March 22, 2020): ~\$1.6T Economic Stimulus package will likely include: (a) \$350B “small business retention loans”; (b) ~\$250B+ initial direct-deposit-checks to all Americans, (initial ~\$3K per household check (\$1K/parent + \$500/child)); (c) “enhanced-unemployment-insurance” (for workers that are laid off); (d) “up to \$4T of liquidity” broad-based lending, (would include impacted-industries, such as commercial airlines; air cargo carriers; cruise lines; potentially Boeing; potentially GE); (e) ~\$110B for hospitals; (f) “small component for airlines and national security companies”. Economic Stimulus package is intended to fund US Economy for next “90-120 days”.

- Must stabilize the economy right now. This is not a multi-year financial crisis. This is a short-term medical emergency. [~50% of economy is small businesses. Workers must be paid]

4. Current Senate ~\$1.6T “CARES” Bill (HR-748) (~580 pages, released Sunday), supports: (a) \$299B small business loans; (b) \$250B unemployment insurance; (c) \$1,200/person tax-credit; (d) six-months of automatic student loan repayments; (e) reduces House’s just-enacted 12 weeks of employee-paid-leave, down to ~two-weeks; (f) \$500B of loan-guarantees, (\$50B commercial air lines; \$8B air cargo carriers; \$17B “loan guarantees critical to national security”; \$425B “for providing liquidity”, (likely Boeing & GE loan source)). [Loan-guarantees prohibit: (a) share repurchases; (b) increases in 2020-2022 executive compensation; (c) any reduction in workforce size; and (d) allows US to take equity/ownership interest for duration of loans, up to five-years]

Also includes potpourri of additional discretionary funding for: (a) ~\$25B Agriculture; (b) ~\$120B HHS; (c) ~\$933M Army National Guard; (d) ~\$557M Air National Guard; (e) ~\$765M Army/USAF/Navy/USMC O&M; (f) ~\$828M DoD-wide O&M; (g) ~\$1B DPA procurement; (h) ~\$2.5B DoD Working Capital Funds; (i) ~\$3.8B Defense Health Program; (j) POTUS authority to extend term of USAF CSAF, (until appointment of successor); (k) ~\$3B DoE Strategic Petroleum Reserve; (l) ~\$20B Education; (m) ~\$19B VA; (n) ~\$10B Transportation/FAA airport grants; (o) ~\$20B Transportation “transit infrastructure grants”; and (p) ~\$16B HUD. [See full program break-out below]

5. **Defense CEOs should be identifying where they have current excess-capacity, and where they can hire significant FTEs by ~summer of 2020; to offset the worst-case ~20% potential unemployment, (in the ~75% (~\$14T) of the private economy, that has been cratered by government-imposed shut-down). Those specific-proposals, with credible projections of actual job-growth, (not just current job-retention), should go right to the front-of-the-line, for accelerated DoD obligation of remaining 2019-2020 defense funding. It is critical to jump-start overall US job-growth.**

Strong immediate three-step punch by USD(A&S) Ellen Lord:

- a. Contractor Progress Payments are immediately-increased to 90%, (from 80%), for large contractors, and 95%, (from 85%), for small contractors.
- b. Contractors are authorized to tele-work.
- c. Contractors are identified as a “Critical Infrastructure Sector” by DHS. DoD cannot over-ride specific-direction from either CDC or state/local authorities, to limit disease-spread. But USD(A&S) Lord is respectfully-asking that CA, WA, and NY state/local authorities, take that into consideration in their quarantine & “stay-at-home” planning.

[See full discussion below]

6. **Boeing formally-suspends its ~\$4.6B/year dividend; plus commits to abstain from share repurchases; plus CEO Dave Calhoun will “forgo all pay until the end of the year”; in preparation for up to ~\$60B of potential Federal secured-loan-guarantees. (Boeing, March 20, 2020).**

- Ambassador Nikki Haley (48) protects her political future, resigning from Boeing Board. (Boeing, March 19, 2020) [“I cannot support a move to lean on the federal government for a stimulus or bailout that prioritizes our company over others and that relies on taxpayers to guarantee our financial position...”]

Boeing is clearly-reacting to commercial airlines slashing of aircraft capacity, (by ~-50%-60%). There is investor fear that cashflow-hemorrhaging airlines will: (a) attempt to refuse delivery of new Boeing Commercial Aircraft for remainder of 2020, (including ~400 stockpiled 737 MAX aircraft); (b) that demand for new BCA aircraft could then potentially be impaired for ~2021-2022 as well; and (c) that airline demand for Aftermarket/spare parts from ~\$18B Boeing Global Services Sector, could also collapse by ~-40%-50% as well.

- Since January 2, 2020, Boeing stock price has plummeted by -71% (-\$238/share), to ~\$95/share.

- ~\$51.9B of total cash was returned to Boeing shareholders during 2015-2019, (CEO Muilenburg's tenure): [\$17.2B 2015-2019 dividends + \$34.7B 2015-2019 share repurchases]

7. SASC approves OSD Nominees (Matt Donovan & Jordan Gillis). UK Farnborough Air Show is cancelled. Senate confirms new Army AMC Commander (Gen. Ed Daly) & ASAALT Military Deputy (LTG Bob Marion).

8. Successful Navy/Army tactical-boost-glide Common-Hypersonic-Glide-Body (C-HGB) "Flight Test Experiment #2" at Pacific Missile Range.

[See full discussion below]

1a. Senate cloture-vote, on Senate's ~\$1.6T Economic Stimulus package, fails on 47:47 Sunday night vote, (60 votes were required). House Speaker Nancy Pelosi announces plans to introduce competing House Bill. (Bloomberg; Politico; USA Today; Washington Examiner; Washington Times, March 22, 2020).

- 1b. Senate Majority Leader Mitch McConnell announces that Senate will re-vote on \$1.6T Economic Stimulus cloture-vote, at ~9:45AM today, with stock market open. (Bloomberg, March 22, 2020).

2a. Sunday Trump press conference on China Virus, (White House, March 22, 2020): [Trump praised CJCS Gen. Mark Milley's intervention to successfully-secure the release of a female hostage, (from undisclosed 3rd country)] [Sen. Rand Paul has also tested positive for virus]

Only ~one in ten Americans, that have symptoms, actually test positive for the virus. [~254K people tested so far, with ~30K confirmed US infections, (~390 deaths)] The US is at-war. Help the worker & protect companies, to protect the US Economy. Projecting that US Economy will spring back in late 2020, "because of pent-up demand".

- HHS will direct all commercial labs on Monday, to prioritize "in-patient" testing, (prioritizing hospital patients & hospital doctors & nurses).
- NY, CA, WA will receive additional National Guard troops, (under State Governor Title 32 authority), (not Federalized). FEMA will fund 100% of cost. State Governors are in-command, with FEMA paying-the-bills.
- NY has received "Major Disaster Declaration", requested by Governor Cuomo. WA "Major Disaster Declaration" was also approved. CA request for "Major Disaster Declaration", was just received. Army Corps of Engineer is building "alternate care sites", (~1,000 beds), for NY. Navy hospital ship USNS Mercy will deploy to Los Angeles, CA. USNS Comfort will deploy to NYC. [Illegal aliens will not be targeted for deportation, if they are tested]

Peter Navarro: White House is currently-using DPA as "quiet-leverage" with industry, because CEOs are already-volunteering. White House will use DPA to forcefully-commandeer any goods from "production-hoarders".

- US will not “nationalize” its private businesses under DPA. US will use DPA to help cut government red-tape, or to commandeer critical stockpiled equipment. CEOs do not want to be nationalized under DPA.

Boeing: “We have to be able to work with Boeing. Boeing was a great company, and will be a great company again, I think shortly...I don’t want stock buy-backs...”

2b. Saturday Trump press conference on China virus, (White House, March 21, 2020): [“Win the war, with as few lives lost as possible”] [“There is tremendous pent-up demand...People are dying to go out to restaurants, and to go on airplanes...”] [~195K diagnostic tests conducted; 19,343 have tested positive. ~50K tests performed on March 20th alone. Testing capacity is now exploding]

148 countries now infected. [China concealed that the Coronavirus is three times more contagious, and ten times more deadly, than the flu. US could have had an additional three-months head-start]

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No corporate share repurchases or executive compensation raises, if you accept federal loans. Money can only be used to keep workers, hire workers, and build facilities.

a. Signed 2nd ~\$104B “Families First Coronavirus Act”, to provide immediate sick leave & free testing. People who have lost their jobs, should continue to receive their paychecks. Keep-the-jobs, keep the pay coming.

b. DPA has been invoked, but the flood of industry volunteers, is precluding the need to issue formal orders to commandeer private industry. (e.g., masks, swabs, sanitizers, ventilators). Hanes Underwear is now retrofitting plants to produce masks, (in addition to 3M and Honeywell). HHS just placed order for “half-billion-dollars of masks”. Even GM, Ford, and Tesla are voluntarily-making ventilators. [~13K ventilators in Strategic National Stockpile; plus “~100K” in hospitals; plus new production; plus anesthesiologist ventilators at outpatient clinics, (can be adapted by changing internal-screens, (FDA is approving now))]

- Supply of “N95 masks” for hospitals has been “vastly-increased...by extending liability protection to [manufacturers] of industrial masks”. [Industrial masks for construction, are perfectly-appropriate for protection of hospital workers]

c. Anecdotal-evidence that Chloroquine (malaria & arthritis drug) and Azithromycin (anti-bacterial “Z-Pack”), can be used together as a therapeutic, to speed recovery.

d. FEMA has-the-lead for coordinating with states, (particularly NY; CA; WA). ~\$100M obligated so far. States should also buy medical supplies internationally, US will reimburse all costs. [Buy America Act will not apply] Locally-executed, state-managed, and federally-funded.

- FEMA is also distributing N95 masks directly from Strategic National Stockpile, to priority hospitals, (NY, CA, WA).

e. Tax day is delayed to July 15, 2020, (instead of April 15, 2020). HUD has suspended all home loan foreclosures for sixty-days, (~8.5M loans). No 2020 Dept. of Education “standardized testing”. Student-loan debt payments are suspended for at least 60 days.

f. VP Pence meets daily with Business Round Table, (which includes most of the major defense primes).

2c. Friday Trump press conference on China virus, (White House, March 20, 2020): Mortality-rate is two-times higher in males, than females. US would look like Italy now, if early China travel-ban had not been implemented. China is in full-scale disinformation campaign. US was not genuinely-informed of risk by China, until ~January 3, 2020.

Just-enacted 2nd ~\$104B Supplemental Act extends manufacturer liability-protection, so that vast-majority of 3M’s ~35M/month industrial/construction N95 masks, can be sold to hospitals, (from only ~5M/month previously), to reduce current mask shortage.

In response to Q&A on ~\$60B Boeing loan request, Trump will support formal prohibition of any corporate share repurchases by federal loan recipients, (because loans are for retaining working, hiring workers, and building facilities; not for enriching CEOs).

Trump has already-placed an order for “millions-of-units” of Chloroquine, (traditional malaria & arthritis drug), because of anecdotal success stories as a therapeutic, (to speed recovery of infected). [“What the hell do we have to lose?”]

- Trump: “Get rid of this invisible enemy...Get rid of it fast...And then go back to the kind of economy that we had...”
- Trump: “When we win this war...we want companies to immediately re-start...”

3. Treasury Sec. Steve Mnuchin, (Fox News Sunday, March 22, 2020): ~\$1.6T Economic Stimulus package will likely include: (a) \$350B “small business retention loans”, (with loan-forgiveness for ~two-weeks of employee-salaries, plus “some Overhead”); (b) ~\$250B+ initial direct-deposit-checks to all Americans, (initial ~\$3K per household check (\$1K/parent + \$500/child), (2nd potential wave of \$3K/household checks would have to come in a subsequent bill); (c) “enhanced-unemployment-insurance” (for workers that are laid off); (d) “up to \$4T of liquidity” broad-based lending, (“Section 133”), (would include impacted-industries, such as commercial airlines; air cargo carriers; cruise lines; potentially Boeing; potentially GE); (e) ~\$110B for hospitals; (f) “small component for airlines and national security companies”. Economic Stimulus package is intended to fund US Economy for next “90-120 days”.

- **Must stabilize the economy right now. This is not a multi-year financial crisis. This is a short-term medical emergency.** [~50% of economy is small businesses. Workers must be paid]
- **Sec. Mnuchin is expecting weak 2Q stock market; 3Q stock market pick-up; and “gigantic fourth quarter” stock market jump.**

4. Current Senate ~\$1.6T “CARES” Bill (HR-748) (~580 pages, released Sunday), supports: (a) \$299B small business loans; (b) \$250B unemployment insurance; (c) \$1,200/person tax-credit; (d) six-months of automatic student loan repayments; (e) reduces House’s just-enacted 12 weeks of employee-paid-leave, down to ~two-weeks; (f) \$500B of loan-guarantees, (\$50B commercial air lines; \$8B air cargo carriers; \$17B “loan guarantees critical to national security”; \$425B “for providing liquidity”, (likely Boeing & GE loan source)). [Loan-guarantees prohibit: (a) share repurchases; (b) increases in 2020-2022 executive compensation; (c) any reduction in workforce size; and (d) allows US to take equity/ownership interest for duration of loans, up to five-years]

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- \$299B Small Business Loans**, (with loan forgiveness for employee payroll; rents; utilities; and interest on mortgage payments); \$700M SBA salaries & expenses; \$265M “Small Business Entrepreneurial Development Programs”.
- ~\$250B unemployment insurance**, (for up to 39 weeks).
- \$1,200 per-person tax credit**, (\$2,400 for joint filing) (+\$500 for each child).
- Employer payroll taxes** are deferred through January 1, 2021.
- Mandates National Academy of Sciences report on “medical product supply chain security”. Also mandates that personal protective equipment and testing kits be included in Strategic National Stockpile.
- Mandatory coverage of diagnostic-testing in all health insurance policies.
- \$1.3B for “Health Centers”**.
- Student loan debt repayments** shall be treated as having been “paid” for the next six-months, (plus no interest accruing during that six-months).
- Reduces the duration of mandatory-paid-leave under “Division E of the Families First Coronavirus Response Act”**, (from House Bill’s just-enacted 12 weeks of employee-paid-leave), to \$511/day (and \$5,110 per employee), **only requiring mandatory-paid-leave for two-weeks** (“80 hours of work”). [Subtitle C, Section 3602]

j. Title IV “Economic Stabilization and Assistance to Severely-Distressed Sectors of the United States Economy”: [Section 4000-4020] **\$500B of loan guarantees (no grants) for:**

- NTE \$50B commercial airlines.
- NTE \$8B cargo air carriers.
- Aviation Excise Taxes are suspended through January 1, 2021.
- NTE \$17B “loan guarantees for businesses critical to maintaining national security”.
- NTE \$425B “for providing liquidity to the financial system that supports lending to eligible businesses, States, municipalities” [Likely Boeing & GE loan source]
- Loans must be shorter than five-years.
- Companies are prohibited from share repurchases, during loan existence.
- Corporate Officer executive compensation is capped at 2019-levels, for March 2020-March 2022.
- Companies must maintain same size (or larger) workforce, as of March 13, 2020. [No RIFs]
- US Government can hold equity ownership in “warrants, stock options, common or preferred stock, or other appropriate equity instruments”.
- Authority to issue new loans expires on December 31, 2020.

For two-year period, DPA Sections 303(a)(6)(C) and 304(e), shall not apply.

For one-year period, DPA Sections 302(d)(1) and 303(a)(6)(B), shall not apply.

k. Agriculture: \$9B Child Nutrition Program; \$15.6B Food Stamps.

l. HHS: ~+\$20B increase in total funding for Commodity Credit Corporation. [See additional HHS discretionary funding below]

m. Commerce: \$1.5B “responding to economic injury”.

n. Justice: \$1B State & Local Law Enforcement.

o. NASA: \$75M.

p. National Science Foundation: \$75M.

q. Army National Guard: \$746M Milper; \$187M O&M.

r. Air National Guard: \$482M Milper; \$75M O&M.

s. Army O&M: \$160M.

t. Navy O&M: \$360M.

u. USMC O&M: \$90M.

v. USAF O&M: \$155M.

w. DoD-wide: \$828M O&M; \$1B DPA Procurement.

x. DoD Working Capital Funds: \$2.5B. [\$1B Navy; \$1B USAF; \$500M Defense Working Capital Fund]

y. Defense Health Program: \$3.8B. [\$3.4B O&M; \$415M RDT&E]

z. General Provisions: Section 13007(c) POTUS may extend term of current CSAF, (Gen. Dave Goldfein), “until the date of the appointment of the successor to such incumbent...”

- aa. DoE: \$3B Strategic Petroleum Reserve.
- bb. Treasury: \$250M “Taxpayer Services”.
- cc. SBA: \$562M SBA “Disaster Loans Program”.
- dd. Interior: \$453M Indian Programs.
- ee. HHS: \$1B Indian Health Services. [Requirement for not-less-than \$450M to be “distributed through tribal shares and contracts with urban Indian organizations”]
- ff. National Endowment for Arts: \$100M grant.
- gg. National Endowment for Humanities: \$100M grant.
- hh. HHS: \$4.5B CDC. [\$1.5B state/local grants]; \$706M National Institute of Allergies and Infectious Diseases; \$425M substance abuse; \$3B “Child Care Development Block Grant”; \$1.1B “Child & Families Services”; \$400M community living programs; \$12.7B “Public Health & Social Services Emergency Fund”, (through Sept. 2024); \$75B “Public Health & Social Services Emergency Fund”, (available until expended).
- ii. Education: \$20B “Education Stabilization Fund”, (primarily state/local grants).
- jj. VA: \$14.4B Veterans Health Administration; \$2.1B “Medical Community Care”; \$606M medical facilities; \$2.3B IT systems.
- kk. State: \$324M; \$95M AID; \$258M “Bilateral Economic Assistance”; \$350M “Migration & Refugee Assistance”; \$88M Peace Corps.
- ll. Transportation: \$10B FAA airport grants; \$20B “Transit Infrastructure Grants”.
- mm. HUD: \$1.25B “Public & Indian Housing”; \$10B “Community Development Fund”; \$4B “Homeless Assistance Grants”; \$1B “Project-Based Rental Assistance”.

5. Defense CEOs should be identifying where they have current excess-capacity, and where they can hire significant FTEs by ~summer of 2020; to offset the worst-case ~20% potential unemployment, (in the ~75% (~\$14T) of the private economy, that has been cratered by government-imposed shut-down). Those specific-proposals, with credible projections of actual job-growth, (not just current job-retention), should go right to the front-of-the-line, for accelerated DoD obligation of remaining 2019-2020 defense funding. It is critical to jump-start overall US job-growth.

Strong immediate three-step punch by USD(A&S) Ellen Lord:

- a. Contractor Progress Payments are increased to 90%, (from 80%), for large contractors, and 95%, (from 85%), for small contractors. [“Class Deviation – Progress Payment Rates”; Acting DPAP Director, Kim Herrington, (DoD, March 20, 2020).
- b. Contractors are authorized to tele-work, consistent with DoD’s previous direction to both uniformed service-members and civilians. [“Contract Place of Performance – Public Health Considerations”; Acting DPAP Director, Kim, Herrington, (DoD, March 20, 2020)

- c. Contractors are identified as a “Critical Infrastructure Sector” by DHS. DoD cannot over-ride specific-direction from either CDC or state/local authorities, to limit disease-spread. But USD(A&S) Lord is respectfully-asking that CA, WA, and NY state/local authorities, take that into consideration in their quarantine & “stay-at-home” planning. [“Defense Industrial Base Essential Critical Infrastructure Workforce”; USD Lord, (DoD, March 20, 2020)]

6. Boeing formally-suspends its ~\$4.6B/year dividend; plus commits to abstain from share repurchases; plus CEO Dave Calhoun will “forgo all pay until the end of the year”; in preparation for up to ~\$60B of potential Federal secured-loan-guarantees. (Boeing, March 20, 2020).

- Boeing formally-endorses ~\$60B of federal “public and private liquidity, including loan guarantees”, (with ~70% (~\$42B) flowing through to its commercial aircraft suppliers). (Boeing, March 17, 2020).
- Ambassador Nikki Haley (48) protects her political future, resigning from Boeing Board. (Boeing, March 19, 2020) [“I cannot support a move to lean on the federal government for a stimulus or bailout that prioritizes our company over others and that relies on taxpayers to guarantee our financial position...As such, I hereby resign my position from the Boeing Board.”]
- Boeing had already drawn-down its new \$13.8B “credit agreement”, to maximize liquidity. (Boeing, March 17, 2020). [Boeing has ~\$27B debt; an additional ~\$10B of cash on-hand; plus additional ~\$9.6B untapped revolving-credit-line]

Boeing is clearly reacting to commercial airlines slashing of aircraft capacity. [United is grounding ~60% of its fleet; Delta is grounding ~70% of its fleet] There is investor fear that cashflow-hemorrhaging airlines will: (a) attempt to refuse delivery of new Boeing Commercial Aircraft for remainder of 2020, (including ~400 stockpiled 737 MAX aircraft); (b) that demand for new BCA aircraft could then potentially be impaired for ~2021-2022 as well; and (c) that airline demand for Aftermarket/parts from ~\$18B Boeing Global Services Sector, could also collapse by ~-40%-50% as well, (as aircraft do not fly; and as older aircraft are simply “parted-out” for spare parts).

Since January 2, 2020, Boeing stock price has plummeted by -71% (-\$238/share), to ~\$95/share.

~\$51.9B total cash was returned to Boeing shareholders during 2015-2019, (CEO Muilenburg’s tenure): [\$17.2B 2015-2019 dividends + \$34.7B 2015-2019 share repurchases]

7. SASC approves nominations of USD(P&R) Matt Donovan, and ASD Sustainment Jordan Gillis. (SASC, March 20, 2020). [Full Senate vote is still to be scheduled]

8. July 20-24, 2020 UK Farnborough Air Show is cancelled, due to Coronavirus. (Farnborough International, March 20, 2020).

9. Senate confirms: (a) Gen. Ed Daly (S) as new Army Materiel Command Commanding General; (b) LTG Flem Walker (S) as new Army AMC Deputy Commanding General; and (c) LTG Bob Marion (S) as new Army ASAALT Military Deputy, (Army, March 20, 2020).

10. Successful Navy/Army tactical-boost-glide Common-Hypersonic-Glide-Body (C-HGB) “Flight Test Experiment #2” at Pacific Missile Range. [Mike White (Asst. Dir. Hypersonics, USD(R&E)); VADM Johnny Wolfe (Navy Strategic Systems Program: C-HGB design-authority); and LTG Neil Thurgood (Army RCCTO: C-HGB production, plus Army LRHW), pose for pictures as proud-parents] (DoD; Inside Defense; Defense News; Aerospace Daily; Defense Daily, March 20, 2020).

From: Wilkie, Robert L., Jr.
Sent: Mon, 23 Mar 2020 14:28:53 +0000
To: RLW
Subject: FW: [MARKETING] [EXTERNAL] What Covid-19 means for global healthcare – FT Live healthcare and life sciences briefing

From: Financial Times Live
Sent: Monday, March 23, 2020 10:27:28 AM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [MARKETING] [EXTERNAL] What Covid-19 means for global healthcare – FT Live healthcare and life sciences briefing

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FINANCIAL TIMES LIVE

Welcome to our quarterly briefing email from FT Live. We would love to hear your thoughts and feedback. Email us at ftlivebriefing@ft.com



**Sarah
Neville**
Global
Pharmac
euticals

When the quarter began, none of us had heard the word **coronavirus**. Three months on, an effort of unparalleled magnitude is underway around the world to stave off multiple deaths from the respiratory disease that was first identified in China's Wuhan province.

Pharma companies have stepped into the breach. For so long reviled for their high prices and untransparent practices, the world is now looking to them to develop an effective vaccine against the disease which threatens to cut a swathe through the global population. **It is a race to be first with a treatment** at a time when, however fast a company is, it can never be quite fast enough.

Even if a vaccine is found, it is of little use without the manufacturing capacity needed to bring it to patients. In an interview with the FT, French drugmaker Sanofi's chief executive, Paul Hudson, and its head of vaccines, David Loew, **called for a European version** of the US government's Biomedical Advanced Research and Development Authority, which works with industry to procure and develop treatments for pandemic influenza and emerging diseases.

As pharma executives confront the challenges of an exceptional era, leadership has never been more important. Both **Pascal Soriot, chief executive of AstraZeneca**, and **Novartis chief executive Vas Narasimhan**, shared their own leadership prescriptions.

But for the foreseeable future, the focus of the industry will remain on a single leadership challenge: defeating a pathogen whose lethal power we have yet to compute fully. Will big pharma, or its smaller cousin the biotech industry, emerge as the heroes of the hour? In another three months we may be closer to knowing the answer to that.

*Read more from the FT on **coronavirus here**. You may also want to sign up to these two FT newsletters:*

Coronavirus business update, to keep you up to date on the impact of the pandemic on business and the global economy.

FT Health, our essential briefing for decision-makers on global health.

FT subscribers sign up **here** | non - FT subscribers register **here**

FT LIVE CORONAVIRUS UPDATE

In view of the rapid escalation of the coronavirus epidemic, FT Live has postponed all events scheduled to take place before the end of June.

We are committed to prioritising the wellbeing of our speakers, sponsors, delegates and staff around the world. We are also aware of the travel restrictions now in place for so many of our participants. We feel therefore that it is in the best interests of all to move all our events to September-December 2020.

If you are registered to attend one of our upcoming events, we will be in touch with you shortly to discuss next steps. Please also keep an eye on the **FT Live website** for new dates.

Thank you so much for your continued support.

Here are some of the healthcare and life sciences events now scheduled from September onwards:

New York | 29 September 2020

FT US PHARMA AND BIOTECH SUMMIT

This event will provide a fresh perspective on the developments impacting the pharma and biotech industries today. Senior industry leaders will share their

insights, ideas and expertise on topics such as pharma pricing and politics, the future of gene editing and the wave of collaboration driving the race for a vaccine for Covid-19.

Find Out More

Boston | 1 October 2020

FT PHARMA AI AND DATA SUMMIT

Artificial intelligence and data analytics are increasingly valuable tools for pharma companies, enabling them to accelerate R&D and unlock the value of products earlier. We will look at how AI can be deployed most effectively in drug discovery, clinical trials and market access.

Find Out More

London | 9-10 November 2020

FT GLOBAL PHARMACEUTICAL AND BIOTECHNOLOGY CONFERENCE

The global pharma industry is at a turning point in its transformation. After years of research, the field of advanced cell and gene therapies is achieving new landmarks, and the reality of curative therapies is here. This event will explore the increasingly complex and uncertain drug pricing environment, manufacturing as the new competitive edge for pharma companies, the potential of AI in drug development and the impact of Covid-19 for different stakeholders across the sector.

Find Out More

IN CASE YOU MISSED IT

FT BUSINESS OF FOOTBALL SUMMIT



Top club and league executives, regulators from media and technology gathered in this month to discuss the financial future of the game at the second annual **FT Business of Football**.

The conference made headlines around the world as Juventus Chairman Andrea Agnelli and Inter Milan President Steven Zhang shared their insights on the coronavirus outbreak and the decision to play games in Italy behind closed doors – Agnelli said this would lead to a “dip” in his club’s income. He also discussed proposals for a Club World Cup and expanded UEFA Champions League, while Zhang outlined his strategy to return Inter to the top of the sport, by targeting revenues and fans in his native China. Read about his business plan in his **interview with the FT**.

Our top video picks:

Video ▶

What happened at FT Business of Football? - FT sports editor Murad Ahmed on the biggest talking points from the day’s event

Video ▶

How to tackle financial inequalities in the game - Alberto Colombo from European Leagues and Tim Williams from Inter Milan on the growing financial polarisation in football, and what to do about it.

EUROPEAN FINANCIAL FORUM



Dublin castle in February, international business leaders, policymakers, regulators and thought leaders discussed developments impacting the financial

Our top video picks:

Video

Sir John Major on Brexit, the UK, the EU and the Future - The former PM called Brexit a “self-inflicted wound” and said the Irish Sea border would store up problems, in an on-stage interview with the FT’s deputy editor Patrick Jenkins.

Video

Geopolitical risk and the impact on global business - Francisco Aristeguieta, chief executive for international business at State Street Corporation, gave a keynote address, outlining the macroeconomic factors and geopolitical risks affecting the operations of global businesses.

RELATED STORIES FROM THE FT



Will coronavirus change how we live?

What seemed like an age of infinite possibility is starting to look much more fragile



Coronavirus could force difficult choices on health systems

The discomfiting idea that some people belong at the front of the queue is already codified



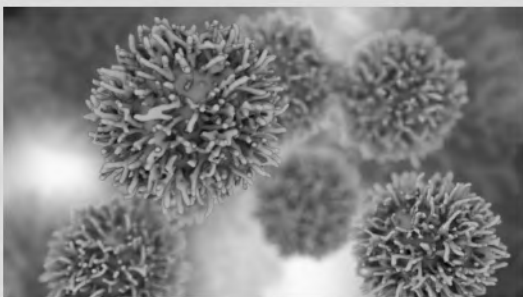
Coronavirus and the collapse of global public health

From clean water to antibiotics and vaccines, the most effective interventions are collective



The shocking coronavirus study that rocked the UK and US

Five charts highlight why Imperial College's research radically changed government policy



Cancer gene map heralds new era of



Why the UK's NHS leads the world

personalised treatment

Scientists complete decade-long project to catalogue mutations that drive disease's development

in managing diabetes

Does mix of innovation and continuity of care make type-2 eradication a 'realistic' ambition?



the west will be hit harder

Oliver Cookson on why the testing response in the west has left western nations catching up with the crisis, and why politics and behaviour are crucial in beating the virus




Impact of childhood obesity

Mapping local 'food environments' to show the link between income, where you live and obesity. Tracking data on shopping and eating habits

SPECIAL REPORTS

How to Build a Healthy City

Today's cities – home to more than half the world's population – are struggling to deal with a harmful mix of public health problems: populations are ageing, obesity is rising and pollution has reached toxic levels.

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FT Health: Combating Diabetes

Over 460m people worldwide have diabetes, a figure that is projected to reach 700m by 2045. This report looks at the factors behind this rise, the latest high-tech solutions, and how health services are coping — or failing to.

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The Future of the Workplace

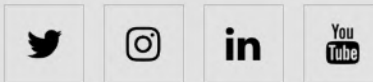
The office is evolving, but are we more productive? We look at what motivates employees and how leaders get things done. Plus: canteens get a refresh, hiring by algorithm, future-proofed corporate culture, and gig work shakes up white-collar jobs.

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Education and Technology

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From: Wilkie, Robert L., Jr.
Sent: Mon, 23 Mar 2020 17:35:11 +0000
To: RLW
Subject: FW: [MARKETING] [EXTERNAL] Countries roll out strict coronavirus restrictions; Trump offers medical assistance to North Korea

From: AEI's Rundown
Sent: Monday, March 23, 2020 1:33:15 PM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [MARKETING] [EXTERNAL] Countries roll out strict coronavirus restrictions; Trump offers medical assistance to North Korea

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The Rundown

A weekly digest of news and analysis from AEI's Foreign and Defense Policy team



The coronavirus continues to sweep across the world, with the global case count increasing by a record magnitude over the weekend. Spain has suffered a 26 percent increase in deaths in the past 24 hours, India and Italy have instituted national lockdowns, Britain reversed course of policy and is largely shutting down, and economies everywhere are upended. The EU is struggling to demonstrate practical solidarity, while Russia is sending military troops and aid to Italy. China has commenced a virulent propaganda campaign accusing the US military of developing and releasing the virus, extolling Xi Jinping's leadership, expelling American journalists, and arguing for the superiority of its repressive governance model over the US. Will free societies prove able to organize effective responses, both to the pandemic and the challenges China poses to the international order? Continue to stay up to date with AEI's scholarship on COVID-19 at our [spotlight page here](#).

Follow us on Twitter [@AEIfdp](#) to keep up with our latest work.

Have a great week,

TWEET OF THE WEEK

Marc Thiessen @marcthiessen

Ayatollah Khomeini joins communist China in spreading conspiracy theory that US created the coronavirus. What do these regimes have in common? An interest in deflecting attention from their miserable handling of the virus.

Retweet

CHINA

The city of Wuhan announced the loosening of its two-month lockdown on Sunday by gradually resuming public transportation and allowing healthy people to return to work.



How serious is the COVID-19 outbreak? Apparently enough to turn China honest, with its National Bureau of Statistics (NBS) describing January–February economic activity as nothing less than a depression. In a new AEIdeas blog, **Derek Scissors** explains that NBS's candid statistics showed that China's industrial output fell 13.5 percent and the services index fell 13 percent. Meanwhile, Beijing expects an upward

trend from the second half of March into April. The Communist Party was stunningly honest about the awful numbers because the blow to prosperity was only short term. [Read more here.](#)

The corona crisis has revealed a deep weakness in the Chinese political system. **Dan Blumenthal** took to the AEIdeas blog to argue that China under the leadership of the Chinese Communist Party (CCP) can hardly govern itself, let alone a new world order. Its economy will suffer through the pandemic, and the Chinese people will be affected by the incompetence and repression of the CCP. And while the CCP will turn its attention to security problems to distract from its internal incompetence, it will not lead a new global order. [Read here.](#)

Americans are practicing social distancing to stop the spread of the coronavirus, unleashed by the Chinese regime's lies and mismanagement. It may also be time to practice social and economic distancing from China as well, argues **Marc Thiessen** in a Washington Post op-ed. The Chinese government's complicity in the coronavirus pandemic is an opportunity for the US to reevaluate its economic ties to Beijing and develop alternative supply chains for medicines and critical technology. China's lies about the virus have us hurtling toward a recession. It is time to immunize our economy and national security from dependence on a deceitful regime. [Continue here.](#)

As businesses and schools across the country close because of the coronavirus, Americans are realizing just how economically dependent we are on China. With a vast majority of our essential and generic drugs running through the country, it's time for Americans to reevaluate the US-China trade relationship. This week, AEI's **Derek Scissors** joined **Danielle Pletka** and **Marc Thiessen** to explain how America became so reliant on China and what we should do to decouple our economies moving forward. [Listen here.](#)

The democratic world order survived the economic crash of 2008, but it may not be so fortunate this time. In a Bloomberg op-ed, **Hal Brands** argues that without better management of the new coronavirus, we might one day look back on 2020 as the moment when Washington's global authority truly began to buckle. The impact of

COVID-19 reveals just how badly America's relative power and prestige have fallen, but there is still a window for Washington to take action. [Learn more here.](#)

EUROPE

On Sunday, German Chancellor Angela Merkel barred groups of more than two people from gathering. Soldiers in Germany, France, and Spain have been deployed across Europe to help build temporary facilities for thousands of coronavirus patients.



The European Union may have survived Brexit, the refugee crisis, and the financial meltdown of 2008, but don't assume COVID-19 can't destroy it. The coronavirus' economic shock could easily exceed that of the 2008 financial crisis, argues **Dalibor Rohac** in a Politico op-ed. European leaders would be foolish to think that the ongoing pandemic is different because it is a public health crisis, rather than a political or financial one. After the quagmire of the Brexit negotiations, it seemed that Europeans had been cured of any desire to leave the EU. While that may have been true a few weeks ago, it can no longer be taken for granted in today's extraordinary times. [Read more here.](#)

Following the publication of Sergei Medvedev's book "The Return of the Russian Leviathan" (Polity, 2019), **Leon Aron** took to The Wall Street Journal to assess Medvedev's views of Russia, concluding that the book marks a new geologic era in Russian politics and foreign policy. Medvedev argues that the Kremlin's foreign policy aims at revenge and glory, making fear Russia's main export, next to oil. But Medvedev never confuses Putin's regime with Russia itself. The current regime, he believes, is not likely to forge anything lasting beyond Putin's life span. [Read the book review here.](#)

The recent parliamentary elections in Slovakia were not about the economy. Rather, they focused on clean governance and more transparent democracy. Economic matters are the most immediate stumbling block for the new government, and as of now, the country is woefully unprepared for the economic shock that is about to hit, argues **Dalibor Rohac** in a Visegrad Insight op-ed. While restoring trust in the government's ability to provide justice is a necessary condition of Slovakia's success, it is not a sufficient one. If the global economic outlook continues to deteriorate, one hopes that the new governing coalition will not resign to complacency or economic nationalism in the region. [Read here.](#)

DEFENSE AND FOREIGN POLICY

Secretary of State Mike Pompeo arrived in Afghanistan on an unannounced visit on Monday in an attempt to mediate the political stalemate between Afghan President Ashraf Ghani and his political rival Abdullah Abdullah.



Although President Donald Trump has declared the coronavirus a national emergency and leading presidential candidate Joe Biden says he would call on the military to deal with it, Defense Department officials are unenthusiastic about the prospect. The Pentagon isn't geared toward taking the lead in a domestic health crisis, and having it do so would be bad for democracy, argues **Kori Schake** in a Bloomberg op-ed. The military should be used for organization and logistics and should be seen as working only in support of civil authorities. The coronavirus may soon require a military response. But the armed forces shouldn't be asked to do more than they are capable of or anything that might threaten America's social fabric and system of governance. [Read it here.](#)

This week, the president invoked the Defense Production Act (DPA) to speed up domestic manufacturing of medical supplies and personal protective equipment needed to combat the coronavirus. But what does that mean? In an AEIdeas blog post, **Mackenzie Eaglen** explains that the broad definition of the DPA allows for military and energy production to be covered under the law's jurisdiction during disasters and emergencies such as COVID-19. While the DPA is invoked by the president, Congress will want to pay close attention to its usage in the coming months to ensure the spirit of the statute is upheld. [Learn more here.](#)

The current pandemic isn't just a danger to public health and the economy; it also threatens our national security infrastructure. In an American Interest op-ed, **Gary Schmitt** notes that given the likely severity of the economic downturn, it seems inevitable that defense budgets will suffer for the sake of economic recovery. As the government works for ways to keep small businesses open, it shouldn't overlook larger companies that employ hundreds of skilled workers who make up the American defense industrial base. It would be perverse if, as a result of coronavirus, the West is not only economically weaker but also less capable of guaranteeing its own security. [Read here.](#)

One year ago, the USS Fort McHenry was quarantined for two months after 25 sailors were infected with the mumps. Now, the US Navy has its first case of coronavirus. It may be difficult for pandemics to reach deployed ships, but it's not impossible, argues **Michael Rubin** in a National Interest op-ed. Just as the coronavirus will cause a fundamental rethink about manufacturing supply chains, its potential spread to other deployed ships and impact on readiness of ships in port will catalyze the Pentagon and its congressional overseers to consider whether the Navy of today is the best force looking forward. [Continue here.](#)

ASIA

On Sunday, President Trump sent a letter to North Korean leader Kim Jong Un to offer assistance in Pyongyang's battle against the coronavirus.



During an emergency like the coronavirus pandemic, does authoritarian rule outshine democracy? In a new Hill op-ed, **Gary Schmitt** and **Michael Mazza** explain that while it is difficult to predict the course of the virus in the US, there is ample evidence that democracies can succeed in averting an epidemic. Just look to Taiwan, which is under constant military threat from China and yet setting the global standard for combating an epidemic. China may be rich and powerful, but the democracy in Taiwan cannot be beat. [Continue here.](#)

After six years in office, Indian Prime Minister Narendra Modi faces the greatest test of his political career: COVID-19. In a new Wall Street Journal op-ed, **Sadanand Dhume** argues that if Modi steers a successful response to coronavirus, he will cement his standing as India's most powerful politician in a generation. But should India suffer a serious outbreak, it could severely diminish his stature and lead to widespread and unpredictable social and political upheaval. [Read it here.](#)

LATIN AMERICA

At least 23 Colombian inmates died in clashes with prison authorities over the weekend after prisoners objected to the lack of response to control the spread of COVID-19. Last week, the US issued a new round of sanctions against the Venezuelan government.



When Uruguayan diplomat Luis Almagro was elected secretary of the Organization of American States (OAS) in 2015, few would have predicted that he would take a hard-line against leftist regimes. Instead, his modest “more rights for more people” became a demand. In a new AEIdeas blog post, **Roger Noriega** notes that many believe the OAS’s commendable new role as a stout defender of democracy and human rights depends on Almagro’s reelection on March 20. If member states choose a secretary general who shrinks back behind ideological lines, the OAS, the region, and its people will pay a dear price. [Read more here.](#)

The dictatorship of Nicolás Maduro in Venezuela will soon face a perfect storm. After several days of denial, the regime has acknowledged the first cases of the coronavirus in the country. In a new Hill op-ed, **Ryan Berg** argues that amid a cratering oil crisis and a slumping global economy, conditions have never been more favorable for the US to strangle the regime and achieve its foreign policy goals in Venezuela. The US must stay vigilant against the regime and trust that external conditions improve its chances of success. [Continue here.](#)

That's a wrap for this week! For more, you can:

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Tips? Comments? Questions? Email Allison Schwartz at allison.schwartz@aei.org.

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This message is for (b)(6) @va.gov | [Manage Preferences](#) | [Unsubscribe](#)

From: Wilkie, Robert L., Jr.
Sent: Mon, 23 Mar 2020 18:51:42 +0000
To: RLW
Subject: FW: [EXTERNAL] Re: VA Abuse & Neglect: A Short Summary

From: (b)(6)
Sent: Monday, March 23, 2020 2:50:05 PM (UTC-05:00) Eastern Time (US & Canada)
To: (b)(6)
(b)(6) Wilkie, Robert L., Jr.; Bonzanto, Dr. Tamara (OAWP); Davis, Lynda; (b)(6)
Subject: [EXTERNAL] Re: VA Abuse & Neglect: A Short Summary

YOU'RE STILL ILLEGALLY DENYING ME MENTAL HEALTH CARE, BECAUSE I AM NOT WILLING TO PARTICIPATE IN YOUR GROUP SHAME CLASS, THAT IS DESIGNED TO ILLEGALLY SLOW VETERANS FROM GETTING TREATMENT.

I will not allow you to hide any longer. I will force you to answer for your harmful practices to veterans. Veterans swore to defend this nation and you are turning your backs on us. You deserve prison!

An Illegally Abused Veteran Who **Will** See Justice,

(b)(6)
(313) 910-(b)(6)
(b)(6)@yahoo.com

On Friday, March 20, 2020, 8:15:39 PM EDT, (b)(6)@yahoo.com> wrote:

I was diagnosed with a degenerative lung disease from the burn pits, after the va called me a liar for over a year. I then had mental health professionals call me a liar, using those same people's libelous notes. After switching to ann arbor va, I was met with resistance and denials. They gave no consideration into the abuse I had already received. Still, I relented and asked for what was being offered, a va mental health provider.

After I did that, I was told that I would have to subject myself to a group shame class, and be paraded around like a circus animal. When I refused and sent more emails, I was given a "phone appointment". I was never called, so I sent another complaint. Shortly after, I received all call from mental health who was upset that I had complained. I made it clear that someone talking to me that way would not try to help I refused to speak with him. Then I was told that I would hear something about a meeting. Again, I was lied to.

I looked in my medical records and see that that mental health "professional" wrote many false statements in his note, portrayed himself as caring and willing to provide care. He claimed I didn't answer, that we spoke for much longer than we did, and that I was unwilling to receive mental health care. None of this is true. That is where my phone records come in. Those will be used to show that the ann arbor va is...ONCE AGAIN TRYING TO CREATE WAYS TO PREVENT ME FROM SEEING A MENTAL HEALTH PROFESSIONAL!

ALL I WANT IS TO SPEAK TO A PSYCHOLOGIST! OVER 3 MONTHS, I'VE BEEN ASKING! Let me speak with a mental health professional in my community. They haven't proven to write libel and negatively affect my health, like the va has. They are actually financially motivated to see me sooner, not intentionally delay care like the va.

(b)(6)
(313) 910-(b)(6)
(b)(6)@yahoo.com

On Wednesday, March 18, 2020, 9:40:37 AM EDT, (b)(6)@yahoo.com> wrote:
Lynda, it's a good thing I didn't hold my breath. The abuse and neglect continues.

(b)(6)
(313) 910-(b)(6)
(b)(6)@yahoo.com

On Friday, March 13, 2020, 9:43:15 AM EDT, Davis, Lynda (b)(6)@va.gov> wrote:
Mr (b)(6)

Let me apologize for any delay in our response to you.
Let me also assure you that our team of service specialists is reviewing your emails right now.
I have specifically asked them to identify options for tele health and community-based assistance in addition to any other care.
I expect you to be hearing from someone soon.
I sincerely hope that you - and your entire family - are well during this time of heightened concern which can indeed be very stressful.
With respect, Lynda Davis

Lynda C. Davis, Ph.D.
Chief, Veteran Experience Officer
Veteran Experience Office
Department of Veteran Affairs
White House / VA Hotline (855) 948-2311
Veterans Crisis Line
Information Line VA311 (844) 698-2311
va.gov/welcome-kit/
Sent with BlackBerry Work
(www.blackberry.com)

From: (b)(6)@yahoo.com>
Date: Friday, Mar 13, 2020, 9:12 AM
To: (b)(6)@va.gov>, (b)(6)
(b)(6)@va.gov>, (b)(6)@va.gov>, (b)(6)
(b)(6)@va.gov>, (b)(6)@va.gov>, (b)(6)
(b)(6)@va.gov>, Wilkie, Robert L., Jr. (b)(6)@va.gov>, Bonzanto, Dr. Tamara
(OAWP) (b)(6)@va.gov>, Davis, Lynda (b)(6)@va.gov>
Subject: [EXTERNAL] VA Advice

I have sent numerous emails the past couple weeks, without any response to my concerns. I have spent the last couple days hoping to receive an email or phone call saying you will allow me to see pulmonary or to see mental health without publicly shaming me first. (Illegal delay tactic) Unfortunately, nothing came.

Attached, you will see my kids' school is cancelled because there is at least 1 **CONFIRMED CORONA VIRUS CASE IN MY CITY**. What would that do to your mental health, if your healthcare was being withheld from you during this? You have intentionally put me in a very dangerous spot, given my lung disease. I begged you people to help. You ignored me.

How many veterans do you think have walked away from your "shame" class and killed themselves? You'll never know, but you clearly do not care about that. I do, though!

(b)(6)
(313) 910 (b)(6)
(b)(6)@yahoo.com

From: Wilkie, Robert L., Jr.
Sent: Mon, 23 Mar 2020 22:25:41 +0000
To: RLW
Subject: FW: [EXTERNAL] Immediate Support

From: (b)(6)
Sent: Monday, March 23, 2020 6:24:25 PM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.; (b)(6)@whitehouse.gov
Subject: [EXTERNAL] Immediate Support

Good Afternoon,

I am writing to see if there are any updates on mortgage payments due to the Corona virus. My current mortgage is through BSI Financial. I am still working on getting my payment in but it being difficult without me working. If you have any suggestions I would appreciate it.

Thank You

(b)(6)
(b)(6) CO (b)(6)
720-951- (b)(6)

From: Wilkie, Robert L., Jr.
Sent: Tue, 24 Mar 2020 01:40:14 +0000
To: RLW
Subject: FW: [EXTERNAL] Request to Review COVID-19 Rapid Response Proposed Solution for VA
Attachments: VSee COVID-19 Proposal.pdf, VSee Green Zone.pptx, Constance Sjoquist Health Industry Advisor 2020.pdf

From: (b)(6)
Sent: Monday, March 23, 2020 8:54:16 PM (UTC-05:00) Eastern Time (US & Canada)
To: Gfrerer, James
Cc: (b)(6)@va.gov; (b)(6) Wilkie, Robert L., Jr.; (b)(6)@va.gov
Subject: [EXTERNAL] Request to Review COVID-19 Rapid Response Proposed Solution for VA

Hi James, (Cc'ing (b)(6)), CEO, VSee, as well as others from the VA)

You may recall me from my work while at HLTH (my background/experience is attached).

I have a company, VSee, who has shared a strategy to expand the response to COVID-19.

Please see the following message (and attachment) from (b)(6) CEO of VSee, on his proposed solution:

Hi (b)(6)

VSee telemedicine is used by Optum, McKesson, Teladoc, Walgreens, Cleveland Clinic, DaVita Health, Sutter Health, and 1500+ others, including NASA Space Station.

VSee was funded by US National Science Foundation, IQT, and Salesforce.com

We would like to create a digital green zone starting for the Veteran's Health Administration.

We have 1M COVID-19 rapid tests available now, with the capacity to increase to 10M tests per week. This is a 5 min antibodies test. This test can be an initial mass screening before the PCR (RNA) test. There is also a mobile app that tracks people's movement and test results, where if a person gets into an area where the other person's test result is unknown - the phone will vibrate as a warning. The idea is like the TSA-Pre - where we track the test results to make sure entire region is safe. The green zone can be expanded week after week until the larger areas are safe.

For the people who test positive or the generally worried population, VSee also has a network of doctors in an Uber-like setup where we can do mass population triage and medicare care, where patients can see a VSee doctor via telemedicine and the drugs will be delivered to their home. This telemedicine network will decrease the number of patients

flooding the hospitals - thereby saving lives.

(b)(6)
650-400-(b)(6)
(b)(6)@vsee.com
<https://vsee.com/>

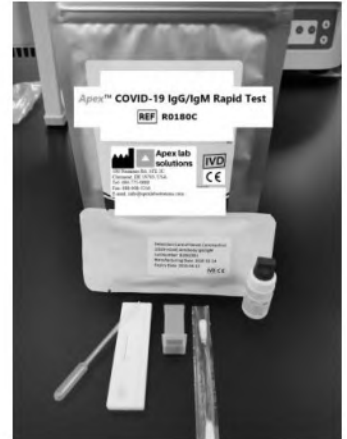
I will leave it to you to connect. Happy to stay in the conversation if helpful.

Kindest regards,

(b)(6)
612-669-(b)(6)
(b)(6)@gmail.com
[https://www.linkedin.com/in/\(b\)\(6\)6](https://www.linkedin.com/in/(b)(6)6)
@ (b)(6)

Airport & Green Zone Solution

- ~50% of corona virus patients do not have fever
- Covid-19 rapid test
 - For screening - 15 min via antibodies (99% accuracy)
 - For release - 6 hour via RNA/DNA (99% accuracy)
 - Highest USA CDC and CLIA certification
- 100% screening for all passengers, crew, and staff
 - Mobile app to track user movement, health, and infection status
 - Show areas of infection to avoid
 - Identify previous infected but recovered patients to fast track screening (positive on antibodies and negative on RNA)
 - Use zero touch infrared thermometer with wireless interface
 - Use zero touch radar sensor to measure the user's pulse and respiratory rates
 - Passenger can board only if negative on antibodies or RNA test



Digital Quarantine Room and Command Center

- Airport digital quarantine rooms to hold passengers tested positive and with preexisting health conditions before transfer to hospital
- Hardware options
 - HD pan, tilt, zoom camera allows medical staff remotely to control the camera and talk and see the patient
 - Vital sign device streaming capture and stream the vital sign monitor to the remote medical staff
- Software
 - VSee Quarantine Room – video call & vital sign streaming
 - VSee Command Center – web interface to allow one staff to monitor 30-50 quarantine rooms



- VSee telemedicine is used by Optum, McKesson, Teladoc, Walgreens, DaVita, Cleveland Clinic, GE Healthcare, and 1500+ others, including NASA Space Station.
- VSee was funded by US National Science Foundation, IQT, and Salesforce.com <https://vsee.com/>
- VSee is working with the Dubai Health Authority, also well as several US organizations and can share specifics, accordingly.

VSee Airport & Greenzone Solution

- ~50% of corona virus patients do not have fever Covid-19 rapid test screening - 15 min via antibodies (99% accuracy) For release - 60 min RNA/DNA (99% accuracy) Highest USA CDC and CLIA certification screening for all passengers, crew, staff Mobile app to track user health, and infection status Show areas of infection to avoid Identify infected but recovered patients to fast track screening (positive on antibodies and negative on RNA) Use zero touch infrared thermometer with wireless interface Use zero touch radar sensor to measure the user's pulse and respiratory rates Passenger can board only if negative on antibodies or RNA test



VSee Digital Quarantine Room

- Airport digital quarantine rooms to hold passengers tested positive and with preexisting health conditions before transfer to hospital
- Hardware options
HD pan, tilt, zoom camera
Allows medical staff remotely to control the camera and talk and see the patient
Vital sign device streaming capture
Capture and stream the vital sign monitor to the remote medical staff
Software
VSee Quarantine Room – video call & vital sign streaming
Command Center – web interface to allow one staff to monitor 30-50 quarantine rooms





MARKET VISION & ALIGNMENT
STRATEGIC CONSULTING SERVICES
COMPETITIVE INTELLIGENCE
CONTENT DEVELOPMENT
PUBLIC SPEAKER
BOARD ADVISOR

[\(b\)\(6\)](https://www.linkedin.com/in/(b)(6))
[\(b\)\(6\)@gmail.com](mailto:(b)(6)@gmail.com)

(b)(6) is one of the preeminent thought leaders in the health industry today. For over 25 years, she has guided companies transforming health through disruptive technologies and forward-thinking business strategies to meet the ever-changing landscape and keep on top of the latest trends and technology advancements.

Most recently (b)(6) was Chief Transformation Officer at HLTH, where she helped create from the ground floor the largest and most important conference for health innovation. As one of the primary architects in shaping the voice and creating the agenda for a new conversation on how to improve health, (b)(6) leveraged her cross-industry insights into a robust platform for market disruption and industry transformation. During her tenure, HLTH grew from just a concept to one the leading industry events with over 6,500 senior leaders spanning every corner of health – payers, providers, pharma, employers, policy-makers, investors, startups, suppliers, retailers, analysts, and associations – and focused on creating the future of health.

Prior to joining HLTH (b)(6) was a healthcare research director at Gartner, where she covered digital platforms, health exchanges, consumer personalization and engagement, and payment integrity and fraud, waste and abuse (FWA) solutions. Prior to joining Gartner, she held senior roles at Optum, United Healthcare, Blue Cross and Blue Shield of MN, and EngagePoint. She is also a member of the ThinkX Board of Advisors. ThinkX uses a patented Px-12™ profile to measure the subconscious algorithms in our thinking to help organizations hire and train top performers.

(b)(6) expertise helps emerging startups and established health organizations focused on improving health – *and the health industry* - to clearly articulate their value proposition and capitalize on the market shifts occurring throughout the entire health ecosystem.

References

- (b)(6) CEO & Founder, HLTH
- (b)(6) CEO, American Telemedicine Association
- (b)(6) Founder & President, m4 Innovation
- (b)(6) Founder, CEO & President, Softheon
- (b)(6) Director, Executive Director, HCEG
- (b)(6) Disruptive Force For Good
- (b)(6) Principal, The Keckley Group
- (b)(6) Healthcare Practice Vice President at Gartner

From: Wilkie, Robert L., Jr.
Sent: Tue, 24 Mar 2020 15:30:34 +0000
To: RLW
Subject: FW: [EXTERNAL] Why is the corporate media taking China's side on the origins of the virus and silencing President Trump?

From: Americans for Limited Government
Sent: Tuesday, March 24, 2020 11:29:49 AM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [EXTERNAL] Why is the corporate media taking China's side on the origins of the virus and silencing President Trump?



March 24, 2020

Permission to republish original opeds and cartoons granted.

Why is the corporate media taking China's side on the origins of the virus and silencing President Trump?

The establishment corporate media, the “narrative readers” and so-called “journalists” have been engaged in an active campaign to distort and hide the efforts of the administration to stem the tide of the Chinese virus and the devastating impact on the economy and the livelihoods of millions of American families. From start to today, the corporate establishment legacy media has taken the side of China. They do assure us all that the massive cash investments made by Chinese front companies into their corporate masters have nothing to do with it. And they are a touch indignant that it is pointed out that they can't seem to be anywhere close to consistent with their politically correct nonsense. When President Trump imposed a travel ban from China — the single most crucial step to slow the spread of the virus in the United States — in January, these provocateurs condemned him. Joe Biden was given a script to attack the travel restrictions as, of course, xenophobic. Likewise, for much of February all mainstream media mouthpieces used the terms “Wuhan Virus” or “Chinese Virus” — right until the Communist Party in China denounced it and demanded it be called by its clinical name. Then, as if a light switch had been flicked, the corporate media denounced anyone — most obviously President Trump — who dared call the virus by its name. It was suddenly “racist” to say China Virus. Still, the latest ploy shows beyond any question their real motivations. Toward

the end of last week, the call went out from the vapid Queen of Leftist Cable — Rachel Maddow — to block President Trump from speaking to the American people.

Cartoon: Twisted

Dems slow down the coronavirus relief package.

The dollar is too strong for the recession that just began, Mr. President

In the wake of coronavirus-induced recession, the dollar is probably far too strong and it could be a key obstacle to a rapid recovery after the virus passes. The Trade Weighted U.S. Dollar Index remains near its highest levels in years. The Great Depression dragged on for years not because of government intervention or tariffs per se, but because of the failure to recognize the adverse impact of keeping the dollar exchange rate to gold so high while the rest of the world was engaged in competitive devaluation and retiring the interwar gold standard. It was this distortion in monetary policy that caused a recession to turn into a massive depression. It was not until the federal government ended the interwar gold standard in 1933 that some relief was felt as unemployment began collapsing. Now, the scourge of deflation could be upon us once again as asset prices plunge after the coronavirus crash. With the global economy essentially frozen while the world waits out the virus, the economy will likely contract massively in first quarter, which ends in a week. Layoffs will be in the millions, and the unemployment rate could be in double digits. To alleviate the long term impacts over the coming months, the Treasury and Federal Reserve should consider doing precisely what the Exchange Stabilization Fund says, which is to stabilize the exchange rate of the dollar versus trade partners during this national emergency. If there ever was a time for a weaker dollar, it's right now, Mr. President. We're going to need all the help we can get.

Video: Senate Dems filibuster coronavirus economic relief bill, hold 30 million small businesses hostage

To incentive Americans to stay in their homes to combat the Chinese coronavirus, Congress needs to provide relief to tens of millions of small businesses, critical industries and the American people. What's the hold up?

Why is the corporate media taking China's side on the origins of the virus and silencing President Trump?



By Bill Wilson

The words "treason" and "traitor" are derived from the Latin *tradere*, "to deliver or hand over". In modern times, "traitor" and "treason" are mainly used with reference to a person helping an enemy in time of war or conflict. From these it is crystal clear that the corporate media in the United States are committing acts of treason on an hourly basis.

As John Nolte of Breitbart News has shown in his meticulous accounting of the outright lies spread by the establishment corporate media, the "narrative readers" and so-called "journalists" have been engaged in an active campaign to distort and hide the efforts of the administration to stem the tide of the Chinese virus and the devastating impact on the economy and the livelihoods of millions of American families.

From the beginning they have been active agents for the Chinese Communist Party. When President Trump imposed a travel ban from China — the single most crucial step to slow the spread of the virus in the United States — in January, these provocateurs condemned him. Joe Biden was given a script to attack the travel restrictions as, of course, xenophobic. And as if signaled on cue, the corporate media dismissed and heaped ridicule on the effort. Today, we

know that the restrictions have played a significant role in slowing the spread and giving us precious time to direct resources to where they are most needed.

Likewise, for much of February all mainstream media mouthpieces used the terms “Wuhan Virus” or “Chinese Virus” — right until the Communist Party in China denounced it and demanded it be called by its clinical name. Then, as if a light switch had been flicked, the corporate media denounced anyone — most obviously President Trump — who dared call the virus by its name. It was suddenly “racist” to say China Virus.

From start to today, the corporate establishment legacy media has taken the side of China. They do assure us all that the massive cash investments made by Chinese front companies into their corporate masters have nothing to do with it. And they are a touch indignant that it is pointed out that they can’t seem to be anywhere close to consistent with their politically correct nonsense.

Still, the latest ploy shows beyond any question their real motivations. Toward the end of last week, the call went out from the vapid Queen of Leftist Cable — Rachel Maddow — to block President Trump from speaking to the American people. Think for one minute about this. The President of the United States is speaking on a regular basis to the people at a time of unprecedented crisis and this extremist calls to have him censored! She is demanding that the corporate media review what he says and they decide what the people should and should not hear.

And, again on cue, the lemmings in the corporate media echo this disgusting demand. The Washington Post’s so-called “media correspondent” Margaret Sullivan issued the same edict in Sunday’s edition of the Post. Almost word for word, Sullivan wants the corporate media to decide.

There is a good reason for this in their view but it has nothing to do with what they are saying. They have to shut down the President for the simple reason that his bold, aggressive defense of the American People is winning him converts in all demographic groups — even among Democrats. The corporate thugs know that Joe Biden is no match for the President, that he only demonstrates more clearly how physically and mentally unfit he is for the office. So, the only way the Maddows and the Sullivans can see to blunt the impact is to silence the President.

It will not happen. And, it cannot be allowed to happen. Lives depend on it. Should this transparent political act happen, should Comcast or Disney or Viacom — owners of the three networks — refuse to air the President’s briefings on the virus, then action should be taken immediately. And what action?

To start the FCC should pull the licenses to broadcast. Harsh? Not really. FDR moved more aggressively against the media in his day. Lincoln went further still. And, to be honest, the

challenge we face today is greater by a large magnitude than the challenges these icons of the political establishment faced.

Shaming and shunning is in order. Every patriot should refuse to comment to, appear on or otherwise engage these fake news purveyors. They only exist because their corporate masters see them as viable vehicles to spread the corporate propaganda line. Take that away from them and they are reduced to the nagging harpies of the insane Left they are. Simply refuse to speak with them. Give them nothing.

And finally, the entire financial structure of these corporate media outlets needs to be reviewed. What subsidies are they getting from federal, state or local governments? To what extent are these corporations based on monopoly arrangements such as Comcast franchise agreements that block competition? What is the nature of their advertising revenue? Does it amount to nothing more than a taxpayer subsidized pass through from elites? Each and every one of these unfair, corporatist supports should be removed.

The time has passed to ignore the threat that corporate control of media poses to the American people. Their servile parroting of the Chinese Communist line, their call for censoring the President of the United States are the final nails in the coffin. Corporate media constitutes a threat to the very survival of our nation and must be addressed accordingly.

Bill Wilson is the President of the Market Research Foundation and a former board member and former President of Americans for Limited Government.

Cartoon: Twisted

By A.F. Branco



[Click here for a higher level resolution version.](#)

The dollar is too strong for the recession that just began, Mr. President



By Robert Romano

The cornerstone of President Donald Trump's plan to defeat the Chinese coronavirus and save potentially millions of lives, and to salvage what can be of the U.S. economy, is a massive expansion of the Treasury's Exchange Rate Stabilization Fund from about \$93 billion to \$500 billion.

These funds will be used to underwrite the economic relief plan, which includes \$300 billion for covering payroll for small businesses, \$200 billion for critical industries and a gigantic expansion of unemployment benefits that amount to paid sick leave for every American who had a job when the virus struck.

These lending and grant programs are essential to incentivize millions of Americans to stay home to combat the virus, and to help the U.S. economy to survive the effects of being shut down during the outbreak response effort. If done correctly, tens of millions of businesses and hundreds of millions of jobs can be saved.

But the Exchange Stabilization Fund has other important, economy-sustaining uses.

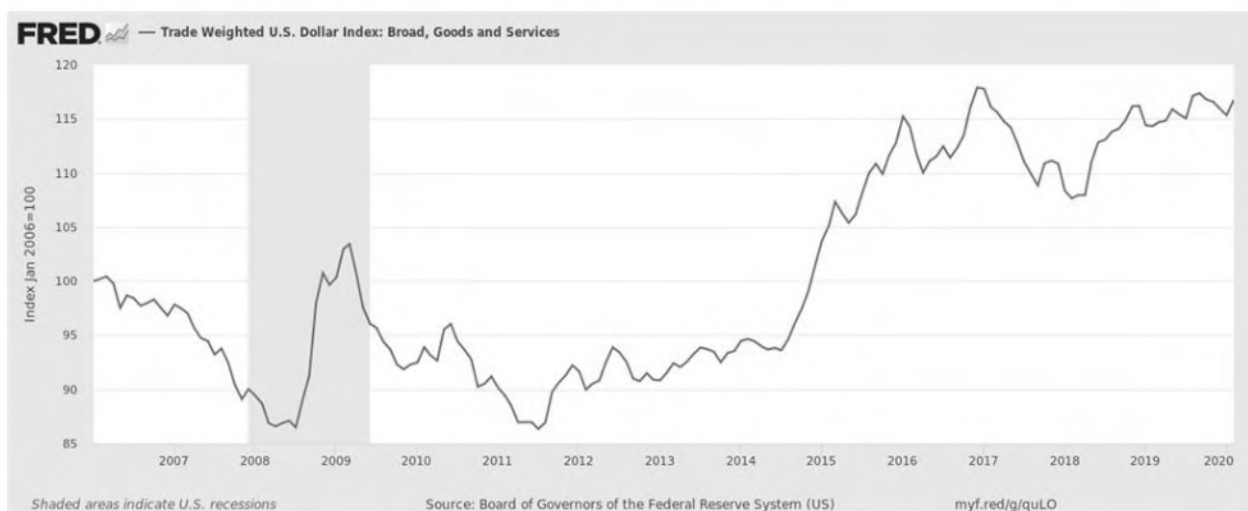
Normally, the U.S. Treasury operates the Exchange Stabilization Fund to "purchase or sell foreign currencies, to hold U.S. foreign exchange and Special Drawing Rights (SDR) assets, and

to provide financing to foreign governments. All operations of the ESF require the explicit authorization of the Secretary of the Treasury ('the Secretary')," [according to Treasury's website](#).

Such funds, with enough firepower, could be used to dump dollars on foreign exchange markets to help weaken the dollar in times of financial stress or if foreign trade partners are engaged in competitive devaluation, exacting deflationary pressure on the U.S. economy.

Like now.

The [Trade Weighted U.S. Dollar Index](#) remains near its highest levels in years. The truth is, the coronavirus could not have struck at a worse time. It means the dollar is really strong compared to overseas trading partners and has been for years.



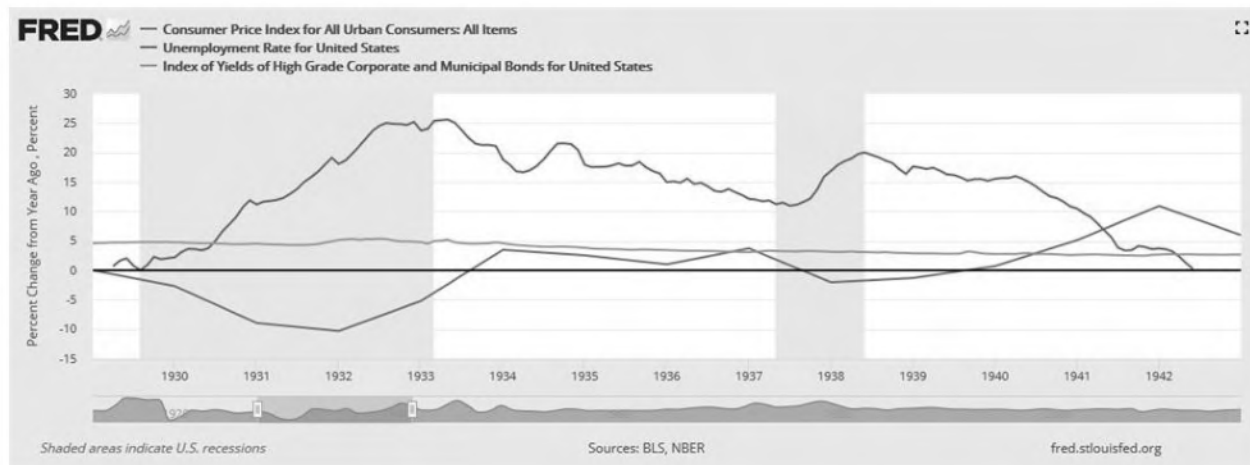
President Trump appears to recognize the problem, but appeared to dismiss the possibility of any intervention on foreign exchange markets, at least for now. On March 23, [he said at the White House to reporters](#), "having a strong dollar is good, but it really sounds good. But the truth is, it makes certain things, like trade, much tougher. And our dollar — I don't know if you've seen, but our dollar has remained very strong, especially against other currencies. Very, very strong. Which, again, makes that trading more difficult, but there's something nice about having a strong dollar, right? You know, no matter what, I'm President. It's nice to have a strong dollar. But it does make trading more difficult."

Right now, however, the dollar is probably far too strong in the wake of the massive recession that just began caused by federal and state governments have practically ordered everything except essential services to be closed.

The Great Depression [dragged on for years](#) not because of government intervention or tariffs per se, but because of the [failure to recognize](#) the adverse impact of keeping the dollar

exchange rate to gold so high while the rest of the world was engaged in competitive devaluation and retiring the interwar gold standard.

It was this distortion in monetary policy that caused a recession to turn into a massive depression.



Deflation in the U.S. began after the great inflation of World War I and the ensuing credit expansion, had a brief respite in the 1920s before beginning again in 1927. It then slowed in 1929, and then went crazy starting in 1930 as banks began failing en masse. Inflation was marked at -2.7 percent in 1930, -8.9 percent in 1931, -10.3 percent in 1932 and -5.2 percent in 1933.

As that occurred, unemployment skyrocketed, reaching 11.2 percent by the end of 1930, up to 19.2 percent by the end of 1931, up to 25 percent in 1932 and peaked in March 1933 at 25.4 percent.

It was not until Franklin Roosevelt ended the interwar gold standard in 1933 that some relief was felt as unemployment began collapsing down to 11 percent by 1937 before spiking again in the 1937-38 recession as deflation ensued again. Ultimately, the ongoing problems were not fully alleviated until the massive mobilization of World War II.

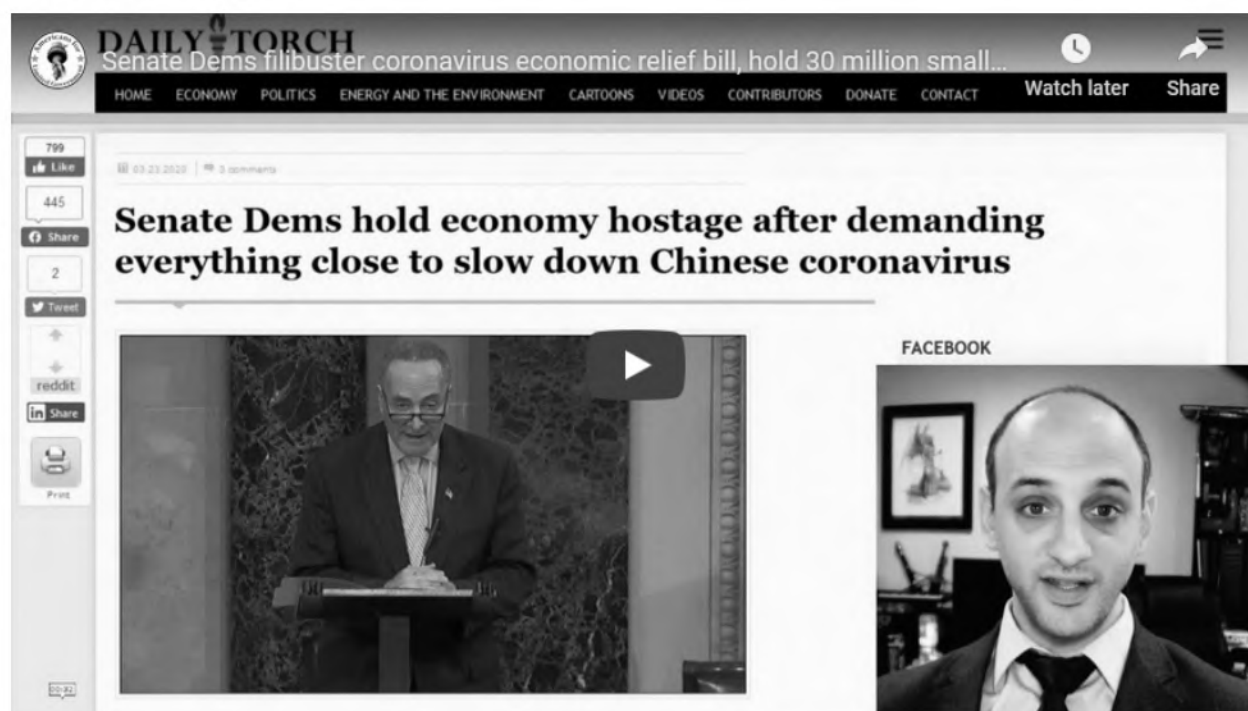
A similar trend appeared to play out during the 2000s leading to the financial crisis, when China's relative low peg to the dollar ultimately coincided with sharp rises in U.S. unemployment and drops in prices, not alleviated until the dollar weakened from 2009 to 2011.

Now, the scourge of deflation could be upon us once again as asset prices plunge after the coronavirus crash. With the global economy essentially frozen while the world waits out the virus, the economy will likely contract massively in first quarter, which ends in a week. Layoffs will be in the millions, and the unemployment rate could be in double digits.

To alleviate the long term impacts over the coming months, the Treasury and Federal Reserve should consider doing precisely what the Exchange Stabilization Fund says, which is to stabilize the exchange rate of the dollar versus trade partners during this national emergency. If there ever was a time for a weaker dollar, it's right now, Mr. President. We're going to need all the help we can get.

Robert Romano is the Vice President of Public Policy at Americans for Limited Government.

Video: Senate Dems filibuster coronavirus economic relief bill, hold 30 million small businesses hostage



To view online: <https://www.youtube.com/watch?v=4lViXCM30VI>

This email is intended for (b)(6)va.gov.
[Update your preferences](#) or [Unsubscribe](#)

From: (b)(6)
Sent: Tue, 24 Mar 2020 19:13:23 +0000
To: RLW
Subject: [EXTERNAL] Fwd: 'Way too early': Health officials warn about perils of restarting economy

(b)(6)

Begin forwarded message:

From: POLITICO Pro Health Care <politicoemail@politicopro.com>
Date: March 23, 2020 at 8:43:22 PM EDT
To: (b)(6)@riponsociety.org
Subject: 'Way too early': Health officials warn about perils of restarting economy
Reply-To: "POLITICO subscriptions" <reply-fe971c727160017c75-553241_HTML-775930271-1376319-339901@politicoemail.com>

'Way too early': Health officials warn about perils of restarting economy

By Adam Cancryn, Nancy Cook

03/23/2020 08:41 PM EDT

Rattled health officials are trying to fight off ascendant voices around Donald Trump pressing the president to restart the economy as soon as Monday to stem severe business and job losses.

The prospect of resuming typical business so soon has horrified these public health leaders, who see the debate as premature amid a crisis that the administration is just beginning to wrangle, according to eight people with knowledge of the administration's discussions about its coronavirus guidelines.

Health experts are contending the fallout will be worse if the White House declares victory now, only to have the virus resurface weeks or months from now. The government, they argue, has yet to definitively answer key questions that would dictate how to reactivate the economy: Do those who recover from coronavirus become immune? How do underlying health conditions affect the severity of the virus? And, most importantly, how widely has it actually spread?

Others have stressed the political risks facing Trump and his reelection campaign if the outbreak worsens significantly, warning that it would be catastrophic if the virus made a comeback closer to the November election — especially after Trump declared himself a “wartime” president and assured the public that his administration was in control.

“It is way too early to even consider rolling back any guidelines,” said Howard Koh, a professor at the Harvard T.H. Chan School of Public Health and former top Obama administration public health official. “With cases and deaths rising by the day, the country must double down, not lighten up, on social distancing and related measures.”

It’s a battle that will intensify in the coming days as the country approaches the end of a 15-day period of extreme social distancing, which the White House launched on March 15.

At a White House briefing Monday night, Trump seemed adamant that the economy would come back to life “very soon,” insisting that the government can fight the viral spread while also going to work — “we can do them both at the same time.”

“Our country wasn’t built to be shut down,” Trump said during a Monday night briefing. “America will again and soon be open for business ... a lot sooner than three or four months that somebody was suggesting, a lot sooner.”

The change in tone comes as a growing faction of people in the White House have started to worry that weeks of economic shutdown will wreak unacceptable financial havoc.

Administration officials like senior adviser Jared Kushner, Trump’s son-in-law, and Treasury Secretary Steven Mnuchin have spent the last few days fielding calls from technology, finance and energy CEOs. These executives have made the case that companies need a clear, concrete date from the White House as to when stores, restaurants and schools can reopen to give the markets and employers a sense of certainty amid the unpredictable spread of the coronavirus.

“To use the analogy of a war, we send kids off to fight a war, and there are deaths associated with it. There will be deaths associated with this,” said Stephen Moore, an informal economic adviser to the Trump administration, who regularly speaks with Trump economic officials. “We are looking at no great options.”

“What is clearly not a viable option is to keep the economy shut down for the next seven to 10 weeks,” he added. “People will lose their life savings, and the unemployment rate will go to 35 percent.”

The internal debate is uniting strange bedfellows from the economic world, with National Economic Council Director Larry Kudlow, trade adviser Peter Navarro, the Wall Street Journal editorial board and the former chief executive of Goldman Sachs Lloyd Blankfein all calling for a quick return to the workplace. Powerful Trump advisers have joined the chorus, including Tom Fitton, president of Judicial Watch, a conservative government accountability group, and Laura Ingraham, a Fox News host.

Not all of Trump’s closest allies agree. Some have advocated for Trump to be as severe as necessary to slow the coronavirus spread.

“Try running an economy with major hospitals overflowing, doctors and nurses forced to stop treating some because they can’t help all, and every moment of gut-wrenching medical chaos being played out in our living rooms, on social media, and shown all around the world,” Republican Sen. [Lindsey Graham](#), a close Trump ally, tweeted on Monday. “There is no

functioning economy unless we control the virus.”

Any lifting of restrictions would happen gradually, people familiar with the discussions said, given the uncertainty about how case counts nationwide could grow over the next several weeks and widespread concerns about hospital capacity.

One option would be for the White House to offer guidance that huge swathes of the country return to business as usual, while hard hit states like New York and Washington remain under a greater lockdown, said three people briefed on the White House’s internal discussions.

Trump touched on the idea during his briefing.

“We can start thinking about as an example, parts of our country are very lightly affected,” he said, citing Nebraska and Idaho as examples.

And even before the end of the 15-day period, Vice President Mike Pence, who is leading the government’s coronavirus task force, said there will soon be new guidance for some first responders and critical infrastructure workers.

“Even if they've been exposed to someone with coronavirus, as long as they don't have symptoms, [these employees] would be able to return to work immediately, wear a mask for two weeks, but otherwise return to the important roles that they play in all our communities,” Pence told reporters during a visit to the Federal Emergency Management Agency.

Still, governors and local leaders will have the ultimate authority over states and cities and the extent to which businesses remain shut down, argued one person familiar with the White House talks, setting up a potential showdown between federal and state officials.

Top administration health officials, including coronavirus response coordinator Deborah Birx, have warned that case numbers are likely to spike in the coming days as testing ramps up. Outside public health experts, meanwhile, emphasize that lags in testing results and reporting mean the government’s data is already about a week behind the reality on the ground.

That’s made it difficult for officials to know how much of an impact the last couple weeks of nationwide social distancing have had on the virus’ spread.

"I can tell you for sure, from a public health standpoint and experience with other outbreaks, we know we are clearly having an effect," said Anthony Fauci, head of the National Institute of Allergy and Infectious Disease, during a White House briefing on Sunday. "But we can't quantitate it for you accurately."

Fauci, a veteran of six presidential administrations, has emerged as a key vessel for health officials’ more cautious views, said one person close to the Health and Human Services Department, due to the broad respect he enjoys inside and outside the administration and his willingness to contradict Trump in public. As the nation’s top infectious disease expert, Fauci has openly advocated for tough distancing measures, reasoning that it’s worth potentially overreacting if it means avoiding a worst-case public health scenario.

That blunt approach has sparked speculation that Fauci could fall out of favor or be sidelined by the president, especially after giving a series of candid interviews detailing his relationship with Trump.

But Fauci's job is not seen as in immediate danger, given his role as one of the few widely trusted officials leading the coronavirus response.

"The president worries most about the stock market," said the person close to HHS. "You want to see a fall in the stock market? Fire Tony Fauci, watch what happens."

The showdown between Trump's economic advisers and public health officials has been building for weeks, as the stock market plummeted and confirmed coronavirus cases climbed, prompting a cascade of restrictions that have disrupted American life and threatened to plunge the nation into a depression.

"You're going to see a clash between the economists and the public health guys, no doubt about it," said one person with knowledge of the debate.

A former HHS official described the situation as a debate between two "horrendous" paths — one that could dramatically remake the economy for the worse by maintaining the current harsh restrictions, and another that could exact a human toll "that will be unacceptable to Americans" if the virus continues spreading for months on end.

"This is like managing a wildfire," the former official said. "There are controlled burns going on right now. The other alternative is just to let the fire run through."

To view online:

<https://subscriber.politicopro.com/health-care/article/2020/03/way-too-early-health-officials-warn-about-perils-of-restarting-economy-1901117>

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This email was sent to (b)(6)@riponsociety.org by:
POLITICO, LLC

1000 Wilson Blvd.
Arlington, VA 22209
USA

From: Wilkie, Robert L., Jr.
Sent: Wed, 25 Mar 2020 11:34:21 +0000
To: RLW
Subject: FW: [EXTERNAL] Deal reached by Congress & White House on ~\$2T Economic Stimulus! Trump will likely re-open parts of the US in "weeks, not months", with stretch-goal of Easter. NYC is the "hot spot". Boeing will pay interest, but not give US Govt. stock...

From: (b)(6)
Sent: Wednesday, March 25, 2020 7:32:34 AM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [EXTERNAL] Deal reached by Congress & White House on ~\$2T Economic Stimulus! Trump will likely re-open parts of the US in "weeks, not months", with stretch-goal of Easter. NYC is the "hot spot". Boeing will pay interest, but not give US Govt. stock own...

Secretary Wilkie:



1. **1:00AM Congressional/White House deal reached on ~\$2T Economic Stimulus package.** (Washington Post; Washington Times; New York Times; Bloomberg; CQ; Seattle Times, March 25, 2020).
2. **Both USD(P&R) Matt Donovan, and Army Under Secretary James McPherson, are confirmed by full Senate vote.** (Senate, March 23, 2020).
- 3a. **Prime-time Trump Fox News "town hall", announcing "stretch-goal" of re-opening significant parts of country by ~Easter, (presumably "west"; "farm-belt"; "much of Texas").** (Rose Garden interview on Fox News, March 24, 2020). [Town Hall also included VP Pence; Dr. Birx; and US Surgeon General, Dr. Jerome Adams] [~320K US tested by mid-day; 46,805 US infected; 593 US deaths]

Trump positions:

- a. **"Luck-or-talent", the early decision to quarantine all travel from China, saved American lives.**
- b. **America was never built to be shut-down. You can destroy a country, by closing it for too long. You pay people to go to work, not to permanently-stay-home. ~37K people die of the flu every year. Be as safe as you can, and then get on with it. Will not destroy ~160M US jobs, (over estimated ~.7% mortality-rate). People need to get used to washing their hands five times a day, and practice social-distancing. That is just a fact-of-life.**
- c. **Keeping the US closed indefinitely, will guarantee that China eventually becomes the largest & most-powerful country in the world. Shutting down the country for at least two weeks, bought time, insight, and new large-scale testing capacity.** [The previous detection system was built to monitor the

seasonal flu. Coronavirus crept-in, with flu-like-symptoms, during the flu season] **Trump believes that US can manage the “hot spots”**.

- **Trump:** “I would love to have it open by Easter...I would love to have it open by Easter...It is such an important day...I would love to have the country opened up, just ‘raring-to-go’ by Easter...” [Easter is April 12, 2020, ~19 days away]
- **Trump:** “I think it is absolutely-possible...People are going to have to practice all of the social-distancing, and don’t shake hands, wash your hands...We have to get our country back to work...This cure is worse than the problem...[M]ore people are going to die, if we allow this to continue...They have their family fortune on the line...They are going to lose their jobs, never to get them back. They are going to lose their businesses, never to get them back...”
- **Trump:** “We want to start up as soon as we can, because we will have a very quick come-back if we do that...If we delay this thing out, you are going to lose more people...Whether we are locked in a room, or whether we are in our office, practicing all of the things...staying away from each other...washing our hands...our country has to get back to work. Otherwise it is going to be very hard to start it up again. We can’t lose the advantage that we have...”
- **US Surgeon General, Dr. Jerome Adams:** “I have been on the Task Force for three-weeks. The President listens to Tony Fauci, he listens to Doctor Birx, he listens when I, or Doctor Carson, or Doctor Hahn, or Doctor Redfield speak up. And he also listens to the Governors...We will assess at the end of the fourteen days, and figure out the most appropriate thing to do. Based on my experience on the Task Force so far, the President will make an appropriate decision, based on all of the data.”

d. **S&P jumped up ~+9% yesterday, and Dow jumped up ~+11% yesterday, because investors were generally-expecting US to remain closed for ~4-5 months.**

- **Trump:** “The Dow was helped...the theory was that we were going to stay out for 4-5 months...You can’t do that...You would destroy our country...We are going to be opening relatively-soon...Our time comes up Monday or Tuesday, the allotted two-weeks...We will stay [closed] a little longer than that, but we want to get open very soon...I also think that the Senate and House...seem to be getting along...”

e. **~\$3K check-per-family, in ~\$1.6T Senate Economic Stimulus package. Small businesses are protected by ~\$350B of loan-guarantees. [~50% of employees work for large businesses. ~50% of employees work for small businesses]**

- **Small business owners must be given a fighting-chance, to save their businesses.** [Trump believes there will be higher suicide-rates from business owners, that simply have their businesses taken away from them, by medical-edict]

f. **US has to protect Boeing.** [“We can’t lose a Boeing...hundreds of thousands of jobs...”]

g. **Metro NY & NJ are testing at ~28% infection-rate, (versus ~7%-8% elsewhere), driven by: (i) population density; (ii) hard surfaces that people touch on the Metro; (iii) well-off people traveled to**

Asia for Christmas; (iv) return of Europeans subsequently. This allowed virus to quietly-expand, until it “got into the older population”.

h. Current mortality-rate is ~1.2% of US patients that have tested-positive. But many people are asymptomatic, or get better without being tested, causing Trump to believe that actual mortality-rate is lower than ~1%.

i. ~90% of people tested, (with symptoms), really only have the flu, and test negative. ~99% of those actually-infected with the Coronavirus, fully-recover.

j. If a person’s body makes an effective anti-body, that person should be immune from getting it again. It is also believed to be seasonal. The potential vaccine would prepare health workers for the 2021 season.

k. Wash your hands; practice social-distancing; avoid groups larger than 10 people; do not eat in restaurants.

l. Trump is also angry that NY previously-turned-down a specific-proposal to buy ~16K ventilators in ~2015 for a potential future pandemic, as too expensive; and is now blaming US Government instead.

3b. Tuesday evening, Trump press conference on virus, (White House, March 24, 2020): “Re-open-by-Easter” is a stretch-goal, with final decision to be based on “hard facts & data”. Trump will likely re-open parts of the US in “weeks, not months”.

[The showman-part-of-Trump, will likely re-open part of the US economy, on Easter Day, (likely “out west”; “farm-belt”; “big sections of Texas”). Dr. Fauci is pushing aggressive testing out into the rest of US, to “see what penetrants are there”. While unspoken, NY, CA, WA, will not be re-opening by Easter. [~370K tested by day-end] [US tested in 8 days, what South Korea tested in eight weeks] [New “self-swabbing-test” will be deployed shortly, to reduce demand for masks & gowns]

a. Good data is finally coming out of Italy. US infected-rate is still jumping, because US is processing several days of back-logged tests, in a single day.

b. NYC is a “hot spot”, with ~56% of all US infected cases, and ~31% of all US deaths. [~1 out of every thousand, appear to be infected] People who fled NYC over the past several days, must immediately self-quarantine, to stop the spread.

c. Expecting ~\$2T compromise Economic Stimulus package, (up from ~\$1.6T Senate Bill, but down from surprise ~\$2.5T March 23rd House Bill). [Distressed-industry loan-guarantees will now be overseen by a formal Board, with an independent IG]

d. ~\$6T total economic stimulus: (a) ~\$2T “direct-assistance” Economic Stimulus package; plus (b) ~\$4T “in Federal Reserve lending-power”.

e. Boeing: Trump: “We will be helping Boeing...”

f. S&P spiked +9%, and Dow spiked ~+11%, on March 24th, because US will re-open for business, within the next “several weeks”, (not ~4-5 months).

g. **Trump's heroes:** Dr. Fauci; Dr. Birx; VADM. Adams; VP Pence; Sec. Steve Mnuchin; Larry Kudlow; Peter Navarro (masks & ventilators).

4. **Sec. Mark Esper**; **CJCS Gen. Mark Milley**; **SEA to CJCS, Ramon Colon-Lopez**, (Virtual Town Hall, March 24, 2020): **This is just another war, that will be fought and won.** [~10K National Guardsmen are already-deployed]

a. Commanders will make the right calls on social-distancing. Listen closely to the chain-of-command, adhere to it, and focus on the mission.

b. Close ally Italy is devastated, but South Korea is recovering. Watching closely for potential breakdown of order within adversaries, (such as Iran).

c. Expecting "moderate-to-low" impacts to Readiness.

d. Must "flatten the infection curve". But cannot execute social-distancing in attack submarines or tanks. Force must remain ready-to-fight.

e. DSD Dave Norquist & VCJCS Gen. John Hyten are on VP Pence's Task Force. NORTHCOM Gen. Terrence O'Shaughnessy is coordinating with the ten FEMA regions.

f. Rumors over potential US martial law, and "mass quarantines", is just poppycock.

g. "Lessons-learned" from China & South Korea are ~8-10 weeks, to drive infection rate down. [Expect "few months long", (~three months). Focus on stomping-out the virus]

h. All troop moves are stopped for sixty-days, (~mid-May), unless an exception is granted, (mission-essential; humanitarian; undue duress/hardship). Will re-evaluate at end of sixty-days.

i. Pentagon will tele-work "for weeks, possibly months". [DoD Network is being beefed-up. Be cautious of cyber "phishing-attempts", and use good cyber-hygiene]

j. Expect deployment of Army field hospitals to Seattle & NYC, (which will then rotate to next-infected-areas).

k. Do not get tested unless you are symptomatic, (flu-like symptoms). If you have flu-like symptoms, get tested right away.

5. **Boeing CEO Dave Calhoun**, (Fox, March 24, 2020): Still expecting 737 MAX return-to-service in "mid-2020". Global commercial airline traffic is down over -70%, with airlines slashing capacity. Short-term Federal shutdown of all US commercial airline travel, almost "appears inevitable".

a. Boeing has to retain its full workforce, (even if it receives no federal aid), because it has to be ready for the upcoming economic recovery.

b. Boeing has ~\$15B of cash on-hand. But credit markets are closed. Credit markets must be re-opened, for Boeing to have liquidity, (~70% of funds pass-down to suppliers). This virus crisis has a clear

beginning, and a visible end. It is a national emergency. It is the job of the US Government to intervene in a national emergency, to re-open the credit markets.

c. Boeing does not want a \$60B "bail-out". ["Calling it corporate welfare is silly."] Boeing wants access to \$60B of one-time liquidity from the US Government. Boeing considers it to be a short-term loan. Consequently, Boeing is refusing to provide US Government with any direct equity/stock ownership of Boeing. But Boeing is willing to pay interest on the \$60B loan. (Fox Business, March 24, 2020).

From: Wilkie, Robert L., Jr.
Sent: Wed, 25 Mar 2020 14:36:05 +0000
To: RLW
Subject: FW: [EXTERNAL] President Trump right to seek balance in moving forward in health emergency

From: Americans for Limited Government
Sent: Wednesday, March 25, 2020 10:33:14 AM (UTC-05:00) Eastern Time (US & Canada)
To: Wilkie, Robert L., Jr.
Subject: [EXTERNAL] President Trump right to seek balance in moving forward in health emergency



March 25, 2020

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President Trump right to seek balance in moving forward in health emergency

The balancing act that President Donald Trump is attempting between public health concerns over the Chinese virus and the economic disaster being left in the wake of the government social distancing flattening the curve cure is perhaps the defining question of his presidency. The health emergency situation should be dramatically different in two to three weeks than it is today, giving the President a pathway to re-opening our nation for business without significantly increasing our collective risk of our medical systems being overrun during the economic re-start. The economic havoc already being wrought by the emergency response cannot be understated. Local small businesses are having their very survival threatened as the fallout from the wise upfront actions of the President to meet the virus head on, and they are exactly why he is pushing hard to create a pathway to open up our nation for business. Killing our nation's economy for a decade with the social distress, increased suicides and drug addiction associated with it is not an acceptable outcome. President Trump wisely has taken measures to slow the spread of the virus over the past two and a third months since it first was diagnosed on our shore, but he now has to move toward balancing the scales so the cure for the disease doesn't kill the patient.

Art of the Deal as Trump secures \$2 trillion economic rescue plan to sustain America

The Senate will complete its bipartisan work on a \$2 trillion economic relief legislative package

today to incentivize Americans to stay home during the Chinese coronavirus outbreak response period, expected to last at least until April 12, Easter Sunday, when President Donald Trump says he'd like to reopen the country if it's safe to do so. Swift passage is expected. To keep everyone sustainably in their homes while we wait out the virus, Congress has produced the largest piece of legislation in American history by a long shot. Fiscal hawks may wish to avert their eyes. The bill will provide \$367 billion for small businesses, \$500 billion for critical industries, cities and states, \$500 billion of additional checks to households that will come atop paychecks or unemployment benefits, \$130 billion for hospitals to fight the outbreak, an additional \$150 billion for state and local governments akin to the Obama stimulus of a decade ago, an additional \$50 billion employee retention tax credit for companies, and the rest will go to a massive expansion of unemployment benefits that amount to paid sick leave for every person who had a job when the virus struck. In the meantime, the Federal Reserve is being given \$4 trillion of new liquidity firepower to address any contagion that enters the financial system during this national emergency. This may be the first attempt to preempt a recession before it happened, preventing potentially hundreds of millions of job losses. If it works, it will be an economic miracle. It could prevent a depression.

Video: VP Pence urges every American household to follow guidelines on coronavirus and what's next?

Vice President Mike Pence is urging every American to follow guidelines to keep their families safe from the Chinese coronavirus at https://www.whitehouse.gov/wp-content/uploads/2020/03/03.16.20_coronavirus-guidance_8.5x11_315PM.pdf

Video: The strong dollar will worsen the coronavirus recession, Treasury should use stabilization fund

The Treasury should consider using its boosted Exchange Stabilization Fund from the economic relief legislation to weaken the dollar against foreign currencies to help shorten the economic downturn brought on by the Chinese coronavirus. Do you think monetary policy should play a role in the government's response effort?

President Trump right to seek balance in moving forward in health emergency



By Rick Manning

The balancing act that President Donald Trump is attempting between public health concerns over the Chinese virus and the economic disaster being left in the wake of the government social distancing flattening the curve cure is perhaps the defining question of his presidency.

In a conference call with Vice President Mike Pence yesterday, I was asked along with other attendees to remind people about the President's Guidelines: 15 Days to slow the spread. But he also stated that the President is looking to end the economic shutdown in weeks not months.

Let's talk about that.

The social distancing hopefully will have had the effect of somewhat limiting the exponential growth of the disease. And while it may seem callous, since the first case was identified on Jan. 14, at this writing there have been fewer than 700 deaths and 55,000 cases. To put this into perspective, an average of about 110 Americans die in car accidents each day. This is not to criticize the decision to shut down flights from China in January, or to shut down flights from Italy and elsewhere in Europe, and to push social distancing along with the cancellation of mass gatherings.

Those were valid decisions based upon the possibility that this Chinese virus could kill as many as one and a half million Americans.

However, since the health emergency has been declared, we have companies like 3M and Hanes producing masks, medical gowns and automakers are turning their assembly lines loose on making needed ventilators. The Defense Department and FEMA are actively setting up field hospitals to back stop the private medical systems capacity, and pharmaceutical manufacturers are moving rapidly toward finding treatments for this nasty little virus. Senior health facilities have been locked down and those who are most vulnerable have been a high priority focus for education and help.

All of these things have happened due to President Trump's system wide approach to dealing with the Chinese created emergency. The President has cut through the bureaucratic red tape to allow new tests that work to be created and widely disseminated (note: it is reported that the Chinese test kits provided to the Czech Republic are generating more false results than correct ones, making it clear that testing without accuracy has no value at all.) Chloroquine is under a mass efficacy test focusing upon health providers, and other meds like Zithromycin are reported to be having positive results around the world. Tens of millions of masks should be produced for U.S. distribution in the next few weeks, and the panic buying should subside so our store shelves will be restocked.

I lay this out because the health emergency situation should be dramatically different in two to three weeks than it is today, giving the President a pathway to re-opening our nation for business without significantly increasing our collective risk of our medical systems being overrun during the economic re-start.

The economic havoc already being wrought by the emergency response cannot be understated. Personally, I have two nephews laid off and my step-brother is having to lay people off from his business.

People like Kim McKenna Johnson who runs One Cross Medical in Campbellsville, Kentucky is helping patients over the phone to overcome their fears, but their waiting rooms are empty because of that same fear. She estimates that her health provider service company will go under in two weeks as they run out of funds to pay staff.

Or, Hector Alvarado who runs an auto detailing company in California. Many of Mr. Alvarado's orders have been cancelled, and like so many others, he cannot afford to be shut down because he is 100 percent self-employed with his family depending upon the income he provides.

These are just two of thousands, if not tens of thousands of local small businesses having their very survival threatened as the fallout from the wise upfront actions of the President to meet the virus head on, and they are exactly why he is pushing hard to create a pathway to open up our nation for business.

Killing our nation's economy for a decade with the social distress, increased suicides and drug addiction associated with it is not an acceptable outcome. President Trump wisely has taken measures to slow the spread of the virus over the past two and a third months since it first was diagnosed on our shore, but he now has to move toward balancing the scales so the cure for the disease doesn't kill the patient.

These are difficult decisions, but it is important that the voices of those whose businesses are at risk and the employees they have had to lay off be heard as part of this national discussion.

America's free enterprise system is proving its greatness as companies are voluntarily moving their production lines to meet the emergency health supply needs without having to be compelled by the federal government. Small businesses have accepted the sacrifices put upon them to meet the crisis, but they should not be forced to shutter their doors, as we move to the next stages in dealing with the health effects of the Chinese virus. Congress needs to act on the CARE Act which provides a lifeline to these businesses, and in the weeks ahead, the President will have to make the very difficult decision on when and how to push the start button on the economy.

To make the decision easier, each of us should follow the guidelines put out by the White House last week for social distancing.

Listen and follow directions of state and local officials;

If you feel sick, stay home, do not go to work and contact your health provider;

If your children are sick, keep them at home, don't send them to school and contact your health provider;

If someone in your house has tested positive, everyone in your household should stay home;

If you're an older person, stay home and away from other people;

If you are a person with a serious underlying health condition that can put you at additional risk, stay home and away from other people.

Let's do the things needed today so America can get back to work tomorrow.

Rick Manning is the President of Americans for Limited Government.

Art of the Deal as Trump secures \$2 trillion economic rescue plan to sustain America while we wait out the virus



By Robert Romano

The Senate will complete its bipartisan work on a \$2 trillion economic relief legislative package today to incentivize Americans to stay home during the Chinese coronavirus outbreak response period, expected to last at least until April 12, Easter Sunday, when President Donald Trump says he'd like to reopen the country if it's safe to do so. Swift passage is expected in the House, too.

The legislation, the subject of intense negotiations for seemingly endless days as the U.S. economy hangs by a thread, businesses cannot meet payroll and layoffs are beginning a huge run-up, comes amid continued uncertainty about the virus' trajectory. On day 15 of the President's national effort to slow the spread, the White House promises an update on where we expect the virus to be in the coming weeks.

To keep everyone sustainably in their homes while we wait out the virus, Congress has produced the largest piece of legislation in American history by a long shot. Fiscal hawks may wish to avert their eyes.

The bill will provide \$367 billion for small businesses, \$500 billion for critical industries, cities and states, \$500 billion of additional checks to households that will come atop paychecks or unemployment benefits, \$130 billion for hospitals to fight the outbreak, an additional \$150 billion for state and local governments akin to the Obama stimulus of a decade ago, an additional \$50 billion employee retention tax credit for companies, and the rest will go to a

massive expansion of unemployment benefits that amount to paid sick leave for every person who had a job when the virus struck.

In the meantime, the Federal Reserve is being given \$4 trillion of new liquidity firepower to address any contagion that enters the financial system during this national emergency.

This may be the first attempt to preempt a recession before it happened, preventing potentially hundreds of millions of job losses. If it works, it will be an economic miracle. It could prevent a depression.

In early April, we'll get the first unemployment report since the country went on lockdown. Without this legislation, double digit unemployment was not out of the question. I doubt it will be a good report either way, although there may be a lapse in the data from when folks were getting laid off and what they were able to report in the survey. What this bill will do is ensure is that the April report that comes out first week of May will be much less bad than it would have been.

President Trump and Congress, if nothing else, can be proud that they are doing everything they can to save as many lives as possible from the virus. Keeping people sustainably in their homes is critical to that effort, and saving as many of the 30 million small businesses who cannot afford to close for a month or so as possible so that the economy has minimal disruption, are all important to protecting our health and our livelihoods in the longer term, too.

This has the potential to save tens of millions of jobs.

For Trump, buoyed by popular approval for his administration's response to the virus, the economic safety net plan will in principle enable his administration and state governors to take as much time as they need to respond to the virus and save as many lives as possible.

Take your time, Mr. President. No rush.

Ultimately, it will be up to states to reopen what's been closed locally. Things like air travel to certain destinations will be resolved federally. In tandem, parts of the economy will begin reopening when we proceed to the next phase.

Vast uncertainty has already been lifted by this deal, hopefully enabling more Americans to stay home and engage in social distancing.

Now, it will be up to the White House to make these benefits immediately available to the American people and businesses. Save them trips to the local unemployment office or bank. There should be a webpage or an app for many of these provisions. Applying should be easy or automatic in the case of tax provisions that Treasury can operate directly.

President Trump needs to tell every business directly that they need not lay anyone off. Really, businesses hold the fate of the recession in their hands. If every one of them take advantage of what's in this legislation, not one person will need to have lost his or her job in the coronavirus outbreak. Continuity in business operations can be provided for.

What might have been a long, deep recession can be a shallow one or not one at all.

That appears to be the plan, anyway. Either way, nobody can say President Trump and Congress did not take this emergency seriously in what they were asking every American to do by staying home and not working. They found a way to sustain us all while the virus response takes place.

Now the job will be to ensure that these measures are actually temporary and end once the economic calamity caused by the virus passes. Stay tuned.

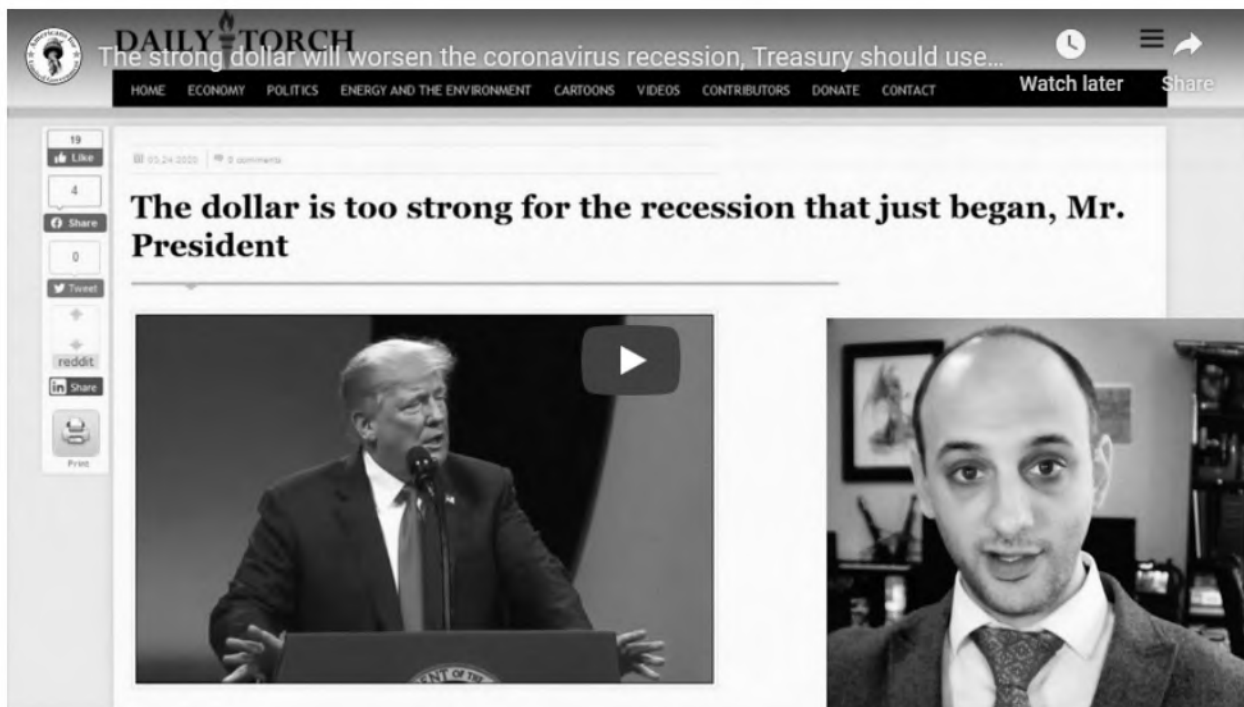
Robert Romano is the Vice President of Public Policy at Americans for Limited Government.

Video: VP Pence urges every American household to follow guidelines on coronavirus and what's next?



To view online: <https://www.youtube.com/watch?v=8IHcYbpl7wA>

Video: The strong dollar will worsen the coronavirus recession, Treasury should use stabilization fund



To view online: <https://www.youtube.com/watch?v=Ud3fSs2zTQ4>

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From: Wilkie, Robert L., Jr.
Sent: Wed, 25 Mar 2020 18:01:46 +0000
To: RLW
Subject: FW: President Trump
Attachments: Screenshot_20200325-112557_Chrome.jpg, Screenshot_20200325-112627_Chrome.jpg

From: Sandra Thornton
Sent: Wednesday, March 25, 2020 1:48:00 PM (UTC-05:00) Eastern Time (US & Canada)
To: Donald Trump Jr.; Donald J. Trump; Eric Trump; Melania Trump; Congressman Gus Bilirakis; Kristen.Sellars@mail.house.gov; Michael.Pence@mail.house.gov; The White House; VHA Client Services Response Team; VAVBAWAS/AMO/DIR; VAVBAWAS/CO/Office of the USB VBA; Wilkie, Robert L., Jr.; Bevins, Debi; Clark, Willie, VBAVACO; IG@mail.whitehouse.gov; Mark.Esper@pentagon.mil; Mark.Esper@pentagon.dod.mil; Matthew.Donovon@pentagon.af.mil
Cc: Hannity@foxnews.com; Sandra Thornton; pkime@militarytimes.com
Subject: [EXTERNAL] President Trump

Sir,

I am a 21 year USAF Veteran, Iraq/Afgh terminally ill Wounded Warrior and I am a deplorable all my life who supports you 100%.

And..I am still fighting the Sec of the VA for my retro disability pay/my dependents educational entitlements x 14 yrs after St Petersburg shred my claim filed before retiring. 8 surgeries, 3 procedures, on 2 machines, lots of notice of disagreements filed, lost my health, lost my finances, job, family, home, slept in my car, hit by Hurricane Michael, lost my honor with countless VA employees breaking federal laws/VA standards, made excels and word documents on my earned pay, past dependents/their status and the VA won't input the correct information into the VA database computer to finish paying my retroactive VA disability pay/pay my 3 past kids educational benefits to me since I paid for these kids because they shred my claim/denied correcting until I won my BVA Appeal 4/1>, yet...St Petes/Reno has ignored federal judge's order. Case precedent was set/established everything I have claimed yet...still not 100% retro paid correctly. I am going to die, especially being high risk with this virus out now...yet this \$255 million dollar VA machine...continues to deny my rights. And to prove the VA hasn't been right...why has it taken 1, 2, 3 times to issue (still wrong) funds? Why did St Petes delete the BVA special processing team's initial audit comment by the BVA federal judge's ruling from FULL/DEA authorized? And...St Petes/Reno repeated did not input dependents data correctly, did not advise me to do DEA forms, deleted dependents, programmed in student vs DEA stipend amounts, continues to use the wrong 9/2018 VA audit dropping my dependents/not putting DEA. The Sec of the VA denied meeting with me on my trip to DC - a terminally ill Wounded Warrior who has lost everything over his federal employees breaking laws/standards and he doesn't want to hear from me? I have spent hundreds of dollars faxing Sec Wilkie/the BVA and still no final resolution. The VA has thrown millions of dollars creating studies, powerpoints, giving briefings on....why Vets will not use their services, why we give up and why we check out...and all they really need to do is look in the mirror then, do the right thing as if they were walking in our shoes for once...but they forget who they work for, they forget why they exist, and they refuse to listen to us/follow laws to save a dollar for nice offices, niceties, bonuses for

those who denied claims, pay increases for those who break laws/are never held accountable, conferences, travel, etc?

Here are a few other VA insights I bet you were never told about Sir:

(Btw...did the VA Sec tell you Sir, the VA changed their my healthVet computer system when Vets message into their providers...it no longer goes right into the Veterans medical records...for accountability, it requires the VA providers to copy/paste into our records now & most do not make it in: same with our telephone messages or making the 24 hr standard to respond)

(And VA Ebenefits there is no method to message in to notify them something is wrong - that was disabled)

(And, have you ever seen the VAs canned letters? No one signs their names thus...again, 0 accountability)

(And did the VA ever tell you in 2011, President Obama directed the VA to make a national data base to include Veterans, active duty, all dependents, civilian employees, contractors, and subcontractors without our knowledge or permission AND states in that federal registry that they can disclose our medical/personal info to federal, state agencies, courts, boards, licensures, IRS, civilian agencies, etc etc etc, it connects at least 16 federal agencies to all of us in this mass national data base which my guess was to continue the mandated Obamacare, again without our knowledge or permission? And...it is/has been up/running and has multiple sites for these data base hubs such as TX, etc? And the VA/HHS/other federal depts have went in/changed HIPPA/Privacy Act of 1974, etc...again, published on gov pages. Breaking US citizens right to privacy. I BET Pres O, the VA, HHS, etc...didn't back brief you and VP Pence on that, didn't they? That system is still running under your Presidency...and it should be destroyed. And then, the VA just added this 10/2019 virtual VA medical/personal database to disclose/coordinated without our permission, unconstitutional.)

I helped kick off the VA Accountability hearings in 12/2013.

I helped get the Airborne bill/Registry started.

I was also a VA Whistleblower under Sec Shinseki on federal laws/VA standards being broken by other employees.

###I am truly exhausted from fighting the VA. I respectfully requesting to meet with President Trump for 5 minutes of your time to address this matter. My son can drive me to DC wherever you are free Sir. I just need a few days notice to be able to get there since I can't fly with my lungs and I I have to stop along the way.

###And lastly, I attached to pictures...Military Times and AF Times, are both telling the world our Military state of readiness which is not..good.

With great respect and admiration,

MSgt Sandra Thornton

USAF 21 yrs

Iraq/Afgh Veteran

Terminally ill Wounded Warrior

Angelsallaroundus@hotmail.com

850-814-5105

From: Donald Trump Jr. <contact@victory.donaldtrump.com>

Sent: Wednesday, March 25, 2020 9:36 AM

To: angelsallaroundus@hotmail.com <angelsallaroundus@hotmail.com>

Subject: My father wants you on his team





Your Military
COVID-19 among troops jumped almost 60 percent this week, as their rate surpasses the U.S. at large

Meghann Myers

📅 1 hour ago







Air Force Times



1 hr · [globe]

That latest data puts service member cases at about 175 per million troops. The rate is higher than the U.S. at large which according to the CDC is sitting at 135 per million as of Wednesday.



MILITARYTIMES.COM

COVID-19 among troops jumped almost 60 percent this week, as their rate surpasses the U.S. at large



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Your Military

COVID-19 among troops jumped almost 60 percent this week, as their rate surpasses the U.S. at large

Meghann Myers



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That latest data puts service mem...



Air Force Times



1 hr ·

That latest data puts service member cases at about 175 per million troops. The rate is higher than the U.S. at large which according to the CDC is sitting at 135 per million as of Wednesday.



MILITARYTIMES.COM

COVID-19 among troops jumped almost 60 percent this week, as their rate surpasses the U.S. at large

Sad

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