

**From:** Ferriter, Karin [Karin.Ferriter@USPTO.GOV]  
**Sent:** 1/28/2019 4:24:35 PM  
**To:** Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]  
**CC:** Ferrey, Seth L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03ec22dd3e8f47c68f0e8c04e30e7462-HHS-Seth.Fe]; Yu, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d80d118c6f7e42eea77511b04486f1fd-HHS-Anne.Yu]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chandrasekera, Ruvani (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=266badb99a8b4d2b90e5b4e019bb0636-HHS-Ruvani.]; Moezie, Minna F. [Minna.Moezie@USPTO.GOV]; Lamm, Marina [Marina.Lamm@USPTO.GOV]; Kostelnik, Summer [Summer.Kostelnik@USPTO.GOV]; ISN-BPS-DL [ISN-BPS-DL@STATE.GOV]; (b)(6) (b)(6) (b)(6) @state.gov; (b)(6) @state.gov; (b)(6) @state.gov; (b)(6) @state.gov; (b)(6) @state.gov; Balliram, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84c90e08bde475889893cf95db919bf-HHS-Richard]; Barna, Lauren (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=271142eac37342bf97e640c7903bb7a1-HHS-Lauren.]; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US [sina.bavari.civ@mail.mil]; Bell, Tammie Jo (CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb3d1b8803c245689b15a0c5cd9cd625-Tammie.Bell]; Berkley, Dale D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2ec3b9be3cc4903a272d25d47ebfb6a-HHS-Berkley]; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-HHS-Gretta.]; Borio, Luciana (EOP.GOV) [luciana.l.borio@nsc.eop.gov]; Brand, Kevin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=980d7ad635e74ede97d34dff3761cf3-HHS-yfb0-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Byrne, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41360f61e1ed49729739326ccbe6eea0-HHS-Patrick]; Cassetti, Cristina G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5a44e839c5642abb30e10feb69800b4-HHS-CCasset]; CBC [CBC@bis.doc.gov]; Chacko, Betsie [betsie.chacko@HQ.DHS.GOV]; Coleman, Kimberly [kimberly.coleman@fema.dhs.gov]; Craig, Allen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=258003fd08cc4d1ba85dc4e70ec3b708-HHS-afc0-cd]; Degruy, Glen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ed115fe668741ae84d51c212ec00d0d-HHS-ivj7-cd]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Epstein, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00aefb9fd4af9ac9e533c8689c202-epsteinj]; Foster, Joseph A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b88c70a10f1843c49dafb981ae48f09c-HHS-jbf7-cd]; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US [cindy.k.fuchs.civ@mail.mil]; Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcd772ee0474055-GarciaM]; Handley, Gray G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c028db015f1f4544ab4c265ec05ad834-HHS-handley]; Harrington, Conor B. EOP/USTR [Conor\_B\_Harrington@ustr.eop.gov]; Healey, Burke L - APHIS [Burke.L.Healey@aphis.usda.gov]; Helfand, Rita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae435981a2b14a1d8b16cfd4c954575f-HHS-rzh7-cd]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US [carl.c.holloway.civ@mail.mil]; Horahan, Kevin (OS) [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebbbcac24c1e47ac888dea10afb73063-HHS-Kevin.H];  
Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar];  
Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI [srjamison@fbi.gov]; Jean-Paul Chretien [Jean-  
Paul\_Chretien@ostp.eop.gov]; Jodi Kouts [Jodi.Kouts@bis.doc.gov]; Jones, Franca R CDR USN DHA HEALTH SURV (US  
[franca.r.jones.mil@mail.mil]; Kapil, Vikas (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b24fd89e78a64022875d565407d5c30a-HHS-vck3-cd]; Kishimori, Jennifer M  
COL USARMY OSD HA (US [jennifer.m.kishimori.mil@mail.mil]; Krause, Philip [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause];  
Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Lamana, Joseph P  
(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9608ab2ee87f4b79ba753036e3d1f3e7-HHS-Joseph.]; Lane, Henry C (NIH)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Lashley-Johnson,  
Deborah [Deborah\_E\_Lashley-Johnson@ustr.eop.gov]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange  
Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa];  
LeButt, Kimberly A CIV OSD OUSD ATL (US [kimberly.a.lebutt.civ@mail.mil]; (b)(6) STATE.GOV  
(b)(6)@state.gov; (b)(6) STATE.GOV (b)(6)@state.gov]; Lueptow, Rebekka (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=944f0156dbf64ffa95cc785bb56ca0f-HHS-Rebekka]; Maher, Carmen  
(FDA/OC) [Carmen.Maher@fda.hhs.gov]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Marinissen, Maria Julia  
(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bad48dfabf84875995b2cad6a6bf46f-HHS-Maria.M]; Marston, Hilary D  
(NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; mcharris@usgs.gov;  
Montgomery, Joel M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b678cd2c99643de9200e8b0a1e4fd44-HHS-ztq9-cd]; Moudy, Robin (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Mowatt, Michael R  
(NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=11dc291d9bdc423e8746678733154767-HHS-MMOWATT]; Music, Francesca  
(MIL) [francesca.c.music2.civ@mail.mil]; Ostlund, Eileen N - APHIS [Eileen.N.Ostlund@aphis.usda.gov]; (U) Pesach  
Lubinsky [pace.lubinsky@fas.usda.gov]; Pallansch, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative  
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2941652b4c784575b079ef1164b4f089-HHS-map1-cd];  
Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Puglielli, Maryann T  
(NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=419865c4977045fbb9eb9ac500edc207-HHS-maryann]; Ranjan, Mukul (NIH)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40fa81127c2042fa913539af005560d6-HHS-MRanjan]; Robert L. Charles  
[robert.l.charles4.civ@mail.mil]; Sanchez, Angela J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=267c51760e9b4c2298df48de8967a08a-HHS-amj4-cd]; Schafer, Julie (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
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[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Schmitt, Beverly J - APHIS  
[Beverly.J.Schmitt@aphis.usda.gov]; (b)(6)@state.gov; Shaw, Michael W (CDC)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5ddc530330f74747b3b7f47e36c4c778-HHS-mws2-cd]; Sherman, Susan (OS)  
[/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Shope, Suzanne  
(CDC/OD/OADS) [awd8@cdc.gov]; Stewart, Jessica L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddbada5915de4419eacb96dfdd49e4687-HHS-Jessica]; (b)(6)  
(STATE.GOV) (b)(6)@state.gov]; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US  
[robert.g.ulrich.civ@mail.mil]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e289444227ae6fec6c226cc55b-HHS-jfv3-cd]; Vinter, Serena (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=994f0f1af6d6491fae1d0788b3667454-HHS-uvv3-cd]; Dominique, Joyelle K (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c948ff2734604738b1e1f739a594902c-HHS-joyelle]; Eisenberg Lobelo, Emily (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729fffd5a474613ae00af6cad651ad-HHS-idq5-cd]; Greene, Carolyn M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5593b7cf42a472096db48fb69f81c85-HHS-cqg4-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Galloway, Summer (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=287a8ac7a6164ea9ac21d2802d45c0d9-HHS-nmd3-cd]; Tucker, Jessica M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0e7c1274cd24987a893a85ee5419e20-HHS-jessica]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcc02744b3a6-HHS-carrie.]; Jorgenson, Lyric A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a83186f3c6b4af1b34e543f7eed8c6-HHS-lyric.j.]; Ramkissoon, Kevin R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a5e66c74db4890994b67a3d1873aca-HHS-kevin.r]

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23 + a few more days

Thank you, Collin, good news on the extension!

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(b)(5)

Karin

**From:** Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>

**Sent:** Monday, January 28, 2019 7:27 AM

**To:** (b)(6)@state.gov; (b)(6)@state.gov; Ferriter, Karin <Karin.Ferriter@USPTO.GOV>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA)

<Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer M COL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; (U) Pesach Lubinsky <pace.lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) (b)(6)@state.gov>; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>

**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Lamm, Marina <Marina.Lamm@USPTO.GOV>; (b)(6) <Summer.Kostelnik@USPTO.GOV>; ISN-BPS-DL <ISN-BPS-DL@STATE.GOV>; Lohman, Danielle C (b)(6)@state.gov>; (b)(6)@state.gov>

**Subject:** Re: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks- For Comment by Jan 23

As a follow up to (b)(6) note, WHO has granted us an extension on the submission deadline to allow us a few more days to submit our comments. They have also let us know that there will be additional opportunities for comments on later versions of the document.

On: 28 January 2019 06:02, (b)(6)@state.gov wrote:

Good morning,

After reviewing the combined comments, (b)(5)

(b)(5)

(b)(5)

Our edits are on top of USPTO's.

For your awareness, we previously sent a note to OGA inquiring about whether the US could have an extension on submitting its comments back to WHO to have more time to adjudicate these interagency comments. The original WHO deadline is COB Monday. If time permits, DOS recommends an additional interagency review on any consolidated USG feedback.

Attached are 3 document:

1) WHO...INTERNAL USE-DOS\_clean-updated (focus on this one);

2) A track change version (This will NOT be sent to WHO. Check here if you have a question about why a comment was deleted/changed – or feel free to call me); and

3) Individual comments on implementation for future use (This will NOT be sent to WHO,

(b)(5)

(b)(5)

Thank you for all of the careful reviews and comments, and a huge thank you OGA for compiling the interagency feedback, as well as my DOS colleagues for their assistance in reviewing!

(b)(6)

Office of International Health and Biodefense  
Bureau of Oceans and International Environmental and Scientific Affairs  
U.S. Department of State

(b)(6)@State.gov

Desk: (b)(6)

**Official - SBU**

**UNCLASSIFIED**

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**From:** (b)(6)@state.gov

**Sent:** Friday, January 25, 2019 12:39 PM

**To:** Karin .Ferriter <Karin.Ferriter@USPTO.gov>; Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana L <Luciana.L.Borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; Foster, Joseph

(CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph <Joseph.Lamana@hhs.gov>; Lane, Cliff <Clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil> (b)(6) @state.gov; (b)(6) @state.gov; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Montgomery, Joel M <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; (U) Pesach Lubinsky <pace.lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov> (b)(6) (b)(6) @state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov> (b)(6) @state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>  
**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence <Lawrence.Kerr@hhs.gov> (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Marina Lamm <Marina.Lamm@USPTO.gov>; Kostelnik, Summer <Summer.Kostelnik@USPTO.GOV>; ISN-BPS-DL <ISN-BPS-DL@STATE.GOV>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Adding State ISN/BPS, lead office for BWC:

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**From:** Ferriter, Karin <Karin.Ferriter@USPTO.GOV>

**Sent:** Friday, January 25, 2019 12:20 PM

**To:** Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana L <Luciana.L.Borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko,

Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; (b)(6) @state.gov; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph <Joseph.Lamana@hhs.gov>; Lane, Cliff <Clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil>; (b)(6) @state.gov; (b)(6) @state.gov; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Montgomery, Joel M <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; (U) Pesach Lubinsky <pace.lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) @state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>; Cc: Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Marina Lamm <Marina.Lamm@USPTO.gov>; Kostelnik, Summer <Summer.Kostelnik@USPTO.GOV>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Collin,

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Our comments are explained in the attachment.

Thank you again for coordinating this.

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(b)(5)

Karin

**From:** Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>

**Sent:** Thursday, January 24, 2019 6:35 PM

**To:** Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <Luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Casseti, Cristina (NIH/NIAID) [E] <ccasseti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; Ferriter, Karin <Karin.Ferriter@USPTO.GOV>; (b)(6) @state.gov; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; Lamm, Marina <Marina.Lamm@USPTO.GOV>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil>; (b)(6) (STATE.GOV) (b)(6) @state.gov; (b)(6) (STATE.GOV) (b)(6) @state.gov; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; Pace.Lubinsky@fas.usda.gov; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) STATE.GOV (b)(6) @state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>;



Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>

**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks- For Comment by Jan 23

Dear Colleagues,

Thank you all for your comments and suggested edits to the WHO Code of Conduct for Pathogen Genetic Sequence Data During Outbreaks document. Before submitting the document tomorrow to WHO around COB, I wanted to share the compiled comments in the attached for everyone's review. I will be going through and removing duplicate comments as well as tomorrow, but wanted to provide time for your review should you be interested in doing so.

Please note that State has included two questions for NIH and USPTO in their comments (the questions are included as comment bubbles in the attached document).

While I have included a column that lists the Department/Agency from which each suggested edit/comment originated, I will be striking this column from the version we submit to WHO, so the comments will not be attributed to individual D/As. I will, however give them the overall list of D/As that submitted comments so they can have a sense of the breadth of expertise/perspectives represented by the comments.

Please also note that although the WHO webpage of the public consultation for this document says submitted comments may be posted publicly, we have asked that WHO not post USG comments publicly to allow our more detailed feedback, which they have agreed to oblige.

Best Regards,

Collin

Collin Weinberger, MPH

Senior Global Health Officer, Office of Pandemics and Emerging Threats

Futrend Technology, Inc (contractor)

Office of Global Affairs

U.S. Department of Health and Human Services

(O): (202) (b)(6) (M): (202) (b)(6)

[collin.weinberger@hhs.gov](mailto:collin.weinberger@hhs.gov)

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**From:** Weinberger, Collin (OS/OGA) (CTR)

**Sent:** Tuesday, January 22, 2019 9:50 AM

**To:** Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; 'Bavari, Sina CIV USARMY MEDCOM USAMRIID (US' <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; 'Beth.N.Harris@aphis.usda.gov' <Beth.N.Harris@aphis.usda.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <CCassetti@niaid.nih.gov>; 'CBC' <CBC@bis.doc.gov>; 'Chacko, Betsie' <betsie.chacko@HQ.DHS.GOV>; 'Coleman, Kimberly' <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <iy7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; 'Ferriter, Karin'

<Karin.Ferriter@USPTO.GOV>; (b)(6)@state.gov; (b)(6)@state.gov; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; 'Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US' <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; 'Harrington, Conor B. EOP/USTR' <Conor\_B\_Harrington@ustr.eop.gov>; 'Healey, Burke L - APHIS' <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; 'Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US' <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; 'Ivan.Zapata@HQ.DHS.GOV' <Ivan.Zapata@HQ.DHS.GOV>; 'Jamison, Selwyn R. (WMD) (FBI' <srjamison@fbi.gov>; 'Jean-Paul Chretien' <Jean-Paul\_Chretien@ostp.eop.gov>; 'Jodi Kouts' <Jodi.Kouts@bis.doc.gov>; 'Jones, Franca R CDR USN DHA HEALTH SURV (US' <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; 'Kishimori, Jennifer MCOL USARMY OSD HA (US' <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; 'Lamm, Marina' <Marina.Lamm@USPTO.GOV>; Lane, Cliff (NIH/NIAID) [E] <CLANE@niaid.nih.gov>; 'Lashley-Johnson, Deborah' <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SIIM) <Theresa.Lawrence@HHS.GOV>; 'LeButt, Kimberly A CIV OSD OUSD ATL (US' <kimberly.a.lebutt.civ@mail.mil>; (b)(6) STATE.GOV; (b)(6)@state.gov; (b)(6) (STATE.GOV) (b)(6)@state.gov; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; 'mcharris@usgs.gov' <mcharris@usgs.gov>; 'Moezie, Minna F.' <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; 'Ostlund, Eileen N - APHIS' <Eileen.N.Ostlund@aphis.usda.gov>; 'Pace.Lubinsky@fas.usda.gov' <Pace.Lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; 'Peter.D.Mamacos@nsc.eop.gov' <Peter.D.Mamacos@nsc.eop.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <MRanjan@niaid.nih.gov>; 'Robert L. Charles' <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; 'Schmitt, Beverly J - APHIS' <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6)@state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) STATE.GOV; (b)(6)@state.gov; 'Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US' <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <Joyelle.Dominique@nih.gov>; Eisenberg, Emily (CDC/OID/NCIRD) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/OID/NCIRD) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/OID/NCIRD) (dbj0@cdc.gov) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Cc: Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; (b)(6)@state.gov; (b)(6)@state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Dear Colleagues,

A friendly reminder to **please send any comments on the WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks by COB tomorrow, January 23rd** so that we can get a compiled set up USG comments back to WHO ahead of their deadline. I have reattached the document and comments form for convenience. Thank you to those of you who have already sent your comments.

Best Regards,  
Collin

<< File: GSDDraftCodeConduct\_forpublicconsultation-v1.pdf >> << File: WHO GSD code of conduct comment-form.docx >>

Collin Weinberger, MPH  
Senior Global Health Officer, Office of Pandemics and Emerging Threats  
Futrend Technology, Inc (contractor)  
Office of Global Affairs  
U.S. Department of Health and Human Services  
(O): (202) (b)(6) (M): (202) (b)(6)  
collin.weinberger@hhs.gov

**From:** Weinberger, Collin (OS/OGA) (CTR)

**Sent:** Thursday, January 3, 2019 9:56 AM

**To:** Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; 'Bavari, Sina CIV USARMY MEDCOM USAMRIID (US' <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; 'Beth.N.Harris@aphis.usda.gov' <Beth.N.Harris@aphis.usda.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <Luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <CCassetti@niaid.nih.gov>; 'CBC' <CBC@bis.doc.gov>; 'Chacko, Betsie' <betsie.chacko@HQ.DHS.GOV>; 'Coleman, Kimberly' <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; 'Ferriter, Karin' <Karin.Ferriter@USPTO.GOV>; (b)(6) @state.gov <(b)(6)@state.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; 'Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US' <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; 'Harrington, Conor B. EOP/USTR' <Conor\_B\_Harrington@ustr.eop.gov>; 'Healey, Burke L - APHIS' <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; 'Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US' <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; 'Ivan.Zapata@HQ.DHS.GOV' <Ivan.Zapata@HQ.DHS.GOV>; 'Jamison, Selwyn R. (WMD) (FBI)' <srjamison@fbi.gov>; 'Jean-Paul Chretien' <Jean-Paul\_Chretien@ostp.eop.gov>; 'Jodi Kouts' <Jodi.Kouts@bis.doc.gov>; 'Jones, Franca R CDR USN DHA HEALTH SURV (US' <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; 'Kishimori, Jennifer MCOL USARMY OSD HA (US' <jennifer.m.kishimori.mil@mail.mil>; 'Korch, George (OS/ASPR/IO' <George.Korch@hhs.gov>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; 'Lamm, Marina' <Marina.Lamm@USPTO.GOV>; Lane, Cliff (NIH/NIAID) [E] <CLANE@niaid.nih.gov>; 'Lashley-Johnson, Deborah' <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SIIM) <Theresa.Lawrence@HHS.GOV>; 'LeButt, Kimberly A CIV OSD OUSD ATL (US' <kimberly.a.lebutt.civ@mail.mil>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; 'mcharris@usgs.gov' <mcharris@usgs.gov>; 'Moezie, Minna F.' <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztd9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; 'Ostlund, Eileen N - APHIS' <Eileen.N.Ostlund@aphis.usda.gov>; 'Pace.Lubinsky@fas.usda.gov' <Pace.Lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; 'Peter.D.Mamacos@nsc.eop.gov' <Peter.D.Mamacos@nsc.eop.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <MRanjan@niaid.nih.gov>; 'Robert L. Charles' <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; 'Schmitt, Beverly J - APHIS' <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov <(b)(6)@state.gov>; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA)

<Jessica.Stewart@hhs.gov> (b)(6) STATE.GOV (b)(6) @state.gov; 'Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US' <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>  
Cc: Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov> (b)(6) @state.gov (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks- For Comment by Jan 23

Dear Colleagues,

WHO has released for comment its *draft code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease* (attached). WHO developed this under the umbrella of the R&D Blueprint and its data and sample sharing work, drawing from experiences during previous outbreaks where sharing of pathogen GSD has been delayed, thereby slowing outbreak and R&D responses. It also comes as WHO is in the process of a broader evaluation of its approach to data and sample sharing, and access and benefit sharing (ABS) as cross-cutting issues. We have been encouraging WHO to take leadership in assessing and explaining the public health impacts of sample sharing and ABS, particularly the public health impacts of the Nagoya protocol, in alignment with our position that issues pertaining to public health should be determined by health experts.

Per WHO:

“Pathogen genetic sequence data (GSD) is an increasingly valuable source of information in understanding and controlling outbreaks of infectious disease. With the advent of next generation sequencing, the depth/extent of available information will expand further. A key concern in recent outbreaks has been variable timelines between the start of an outbreak and the public availability of the first and subsequent genetic sequences. WHO strongly supports public access to sequence data to inform public health and research decision-making during outbreaks, the equitable sharing of benefits derived from the use of such data, and the legitimate interests of data providers. WHO has consulted with many stakeholders and institutions working in the pathogen sequencing arena, including those who have been involved in applications to recent outbreaks. Based on these consultations, and on lessons learned from recent outbreaks as part of the data sharing workstream of the WHO R&D Blueprint, WHO is proposing elements of a code of conduct for GSD sharing in infectious disease outbreaks.

Through this code of conduct WHO seeks to contribute towards an enabling environment for sharing of pathogen GSD where equitable benefit sharing and the needs of data providers around the world can be addressed so that rapid international sharing of sequence data can occur consistently, in accord with IHR 2005, allowing public health authorities, product developers and researchers to collaborate more effectively from a position of mutual trust with respect for submitters’ rights to the information they provide.”

WHO is asking for stakeholders to provide comments via the attached comment form by January 28. **I would be happy to consolidate USG comments and send them all together in a single compiled document if you please send me your comments by COB Wednesday, January 23, 2019.**

If there are strong concerns around the document, we can organize a call in coordination with the leads of the USG Sample Sharing Working Group and our colleagues at State IHB to discuss our approach to providing feedback, perhaps considering drafting a summary document outlining our concerns as Ruvani suggested last week as opposed to simply providing comments via the comment form.

Best Regards,

Collin

<< File: GSDDraftCodeConduct\_forpublicconsultation-v1.pdf >> << File: WHO GSD code of conduct comment-form.docx >>

Collin Weinberger, MPH

Senior Global Health Officer, Office of Pandemics and Emerging Threats

Futrend Technology, Inc (contractor)  
Office of Global Affairs  
U.S. Department of Health and Human Services  
(O): (202) (b)(6) (M): (202) (b)(6)  
[collin.weinberger@hhs.gov](mailto:collin.weinberger@hhs.gov)

**From:** (b)(6)@state.gov]  
**Sent:** 1/28/2019 8:02:21 AM  
**To:** Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; (b)(6)@state.gov]; (b)(6)@state.gov]; Karin.Ferriter [Karin.Ferriter@USPTO.gov]; Balliram, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84c90e08bdbe475889893cf95db919bf-HHS-Richard]; Barna, Lauren (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=271142eac37342bf97e640c7903bb7a1-HHS-Lauren.]; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US [sina.bavari.civ@mail.mil]; Bell, Tammie Jo (CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb3d1b8803c245689b15a0c5cd9cd625-Tammie.Bell]; Berkley, Dale D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2ec3b9be3cc4903a272d25d47ebfb6a-HHS-Berkley]; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-HHS-Gretta.]; Borio, Luciana L [Luciana.L.Borio@nsc.eop.gov]; Brand, Kevin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=980d7ad635e74ede97d34dff3761cf3-HHS-yfb0-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Byrne, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41360f61e1ed49729739326ccbe6eea0-HHS-Patrick]; Cassetti, Cristina G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5a44e839c5642abb30e10feb69800b4-HHS-CCasset]; CBC [CBC@bis.doc.gov]; Chacko, Betsie [betsie.chacko@HQ.DHS.GOV]; Coleman, Kimberly [kimberly.coleman@fema.dhs.gov]; Craig, Allen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=258003fd08cc4d1ba85dc4e70ec3b708-HHS-afc0-cd]; Degruy, Glen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ed115fe668741ae84d51c212ec00d0d-HHS-ivj7-cd]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Epstein, Jay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00aeaafbff9fd4af9ac9e533c8689c202-epsteinj]; Foster, Joseph A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b88c70a10f1843c49dafb981ae48f09c-HHS-jbf7-cd]; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US [cindy.k.fuchs.civ@mail.mil]; Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcd772ee0474055-GarciaM]; Handley, Gray G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c028db015f1f4544ab4c265ec05ad834-HHS-handley]; Harrington, Conor B. EOP/USTR [Conor\_B\_Harrington@ustr.eop.gov]; Healey, Burke L - APHIS [Burke.L.Healey@aphis.usda.gov]; Helfand, Rita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae435981a2b14a1d8b16cfd4c954575f-HHS-rzh7-cd]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US [carl.c.holloway.civ@mail.mil]; Horahan, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebbbca24c1e47ac888dea10afb73063-HHS-Kevin.H]; Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d54da69787255ca964affa-HHS-Rosemar]; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI [srjamison@fbi.gov]; Jean-Paul Chretien [Jean-Paul\_Chretien@ostp.eop.gov]; Jodi Kouts [Jodi.Kouts@bis.doc.gov]; Jones, Franca R CDR USN DHA HEALTH SURV (US [franca.r.jones.mil@mail.mil]; Kapil, Vikas (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24fd89e78a64022875d565407d5c30a-HHS-vck3-cd]; Kishimori, Jennifer M COL USARMY OSD HA (US [jennifer.m.kishimori.mil@mail.mil]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Lamana, Joseph P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9608ab2ee87f4b79ba753036e3d1f3e7-HHS-Joseph.]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Lashley-Johnson, Deborah [Deborah\_E\_Lashley-Johnson@ustr.eop.gov]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; LeButt, Kimberly A CIV OSD OUSD ATL (US [kimberly.a.lebutt.civ@mail.mil]; (b)(6)@state.gov]; (b)(6)@state.gov]; Lueptow, Rebekka (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=944f0156dbf64ffaa95cc785bb56ca0f-HHS-Rebekka]; Maher, Carmen (FDA/OC) [Carmen.Maher@fda.hhs.gov]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Marinissen, Maria Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5bad48dfabf84875995b2cad6a6bf46f-HHS-Maria.M]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; mcharris@usgs.gov; Montgomery, Joel M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b678cd2c99643de9200e8b0a1e4fd44-HHS-ztq9-cd]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Mowatt, Michael R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=11dc291d9bdc423e8746678733154767-HHS-MMOWATT]; Music, Francesca [francesca.c.music2.civ@mail.mil]; Ostlund, Eileen N - APHIS [Eileen.N.Ostlund@aphis.usda.gov]; (U) Pesach Lubinsky [pace.lubinsky@fas.usda.gov]; Pallansch, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2941652b4c784575b079ef1164b4f089-HHS-map1-cd]; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Puglielli, Maryann T (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=419865c4977045fbb9eb9ac500edc207-HHS-maryann]; Ranjan, Mukul (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=40fa81127c2042fa913539af005560d6-HHS-MRanjan]; Robert L. Charles [robert.l.charles4.civ@mail.mil]; Sanchez, Angela J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=267c51760e9b4c2298df48de8967a08a-HHS-amj4-cd]; Schafer, Julie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad453f0426b24a52bef9d08e1fef7967-HHS-Julie.S]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Schmitt, Beverly J - APHIS [Beverly.J.Schmitt@aphis.usda.gov]; (b)(6)@state.gov]; Shaw, Michael W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5ddc530330f74747b3b7f47e36c4c778-HHS-mws2-cd]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Shope, Suzanne (CDC/OD/OADS) [awd8@cdc.gov]; Stewart, Jessica L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ddbada5915de4419eacb96dfdd49e4687-HHS-Jessica]; (b)(6)@state.gov]; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US [robert.g.ulrich.civ@mail.mil]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Vinter, Serena (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=994f0f1af6d6491fae1d0788b3667454-HHS-uvv3-cd]; Dominique, Joyelle K (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c948ff2734604738b1e1f739a594902c-HHS-joyelle]; Eisenberg Lobelo, Emily (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729ffed5a474613a4e00af6cad651ad-HHS-idq5-cd]; Greene, Carolyn M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e5593b7cf42a472096db48fb69f81c85-HHS-cqg4-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3dd3de35d489aa4012b73d93f133f-HHS-dbj0-cd]; Galloway, Summer (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=287a8ac7a6164ea9ac21d2802d45c0d9-HHS-nmd3-cd]; Tucker, Jessica M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0e7c1274cd24987a893a85ee5419e20-HHS-jessica]; Wolinetz, Carrie D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4c547ca11976474a8fdcfcc02744b3a6-HHS-carrie.]; Jorgenson, Lyric A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad83186f3c6b4af1b34e543f7eed8c6-HHS-lyric.j]; Ramkissoon, Kevin R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c5a5e66c74db4890994b67a3d1873aca-HHS-kevin.r]  
**CC:** Ferrey, Seth L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03ec22dd3e8f47c68f0e8c04e30e7462-HHS-Seth.Fe]; Yu, Anne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d80d118c6f7e42eea77511b04486f1fd-HHS-Anne.Yu]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chandrasekera, Ruvani (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=266badb99a8b4d2b90e5b4e019bb0636-HHS-Ruvani.]; Moezie, Minna F. [Minna.Moezie@USPTO.GOV]; Marina Lamm [Marina.Lamm@USPTO.gov]; Kostelnik, Summer [Summer.Kostelnik@USPTO.GOV]; ISN-BPS-DL [ISN-BPS-DL@STATE.GOV]; (b)(6) (b)(6)@state.gov; (b)(6) (Geneva) (b)(6)@state.gov  
**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Thanks. I strongly support the overall approach proposed by (b)(6)

(b)(6)

**Official**  
**UNCLASSIFIED**

**From:** Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>

**Sent:** Monday, January 28, 2019 7:27 AM

**To:** (b)(6)@state.gov; (b)(6)@state.gov; Karin.Ferriter <Karin.Ferriter@USPTO.gov>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana L <Luciana.L.Borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US



<jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph <Joseph.Lamana@hhs.gov>; Lane, Cliff <Clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil> (b)(6) @state.gov> (b)(6) @state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Montgomery, Joel M <zqt9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; (U) Pesach Lubinsky <pace.lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov> (b)(6) @state.gov>; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov> (b)(6) @state.gov>; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>  
**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence <Lawrence.Kerr@hhs.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Marina Lamm <Marina.Lamm@USPTO.gov>; Kostelnik, Summer <Summer.Kostelnik@USPTO.GOV>; ISN-BPS-DL <ISN-BPS-DL@STATE.GOV> (b)(6) @state.gov>; (b)(6) @state.gov>; (b)(6) (Geneva) (b)(6) @state.gov>

**Subject:** Re: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks- For Comment by Jan 23

As a follow up to (b)(6) note, WHO has granted us an extension on the submission deadline to allow us a few more days to submit our comments. They have also let us know that there will be additional opportunities for comments on later versions of the document.

On: 28 January 2019 06:02 (b)(6) @state.gov> wrote:

Good morning,

After reviewing the combined comments (b)(5)

(b)(5)

(b)(5)

Our edits are on top of USPTO's.

For your awareness, we previously sent a note to OGA inquiring about whether the US could have an extension on submitting its comments back to WHO to have more time to adjudicate these interagency comments. The original WHO

deadline is COB Monday. If time permits, DOS recommends an additional interagency review on any consolidated USG feedback.

Attached are 3 document:

- 1) WHO...INTERNAL USE-DOS\_clean-updated (focus on this one);
- 2) A track change version (This will NOT be sent to WHO. Check here if you have a question about why a comment was deleted/changed – or feel free to call me); and
- 3) Individual comments on implementation for future use (This will NOT be sent to WHO, (b)(5))

(b)(5)

Thank you for all of the careful reviews and comments, and a huge thank you OGA for compiling the interagency feedback, as well as my DOS colleagues for their assistance in reviewing!

(b)(6)

Office of International Health and Biodefense  
Bureau of Oceans and International Environmental and Scientific Affairs  
U.S. Department of State

(b)(6) @State.gov

Desk: (b)(6)

**Official - SBU**

**UNCLASSIFIED**

**From:** (b)(6) @state.gov>

**Sent:** Friday, January 25, 2019 12:39 PM

**To:** Karin .Ferriter <Karin.Ferriter@USPTO.gov>; Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana L <Luciana.L.Borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI) <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph <Joseph.Lamana@hhs.gov>; Lane, Cliff <Clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil>; (b)(6) @state.gov>; (b)(6) J@state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov;

Montgomery, Joel M <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; (U) Pesach Lubinsky <pace.lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) M@state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>  
**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Marina Lamm <Marina.Lamm@USPTO.gov>; Kostelnik, Summer <Summer.Kostelnik@USPTO.GOV>; ISN-BPS-DL <ISN-BPS-DL@STATE.GOV>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Adding State ISN/BPS, lead office for BWC:

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**From:** Ferriter, Karin <Karin.Ferriter@USPTO.GOV>

**Sent:** Friday, January 25, 2019 12:20 PM

**To:** Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana L <Luciana.L.Borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; (b)(6) @state.gov; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph <Joseph.Lamana@hhs.gov>; Lane, Cliff <Clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US

<kimberly.a.lebutt.civ@mail.mil> (b)(6) @state.gov (b)(6) @state.gov; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Montgomery, Joel M <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; (U) Pesach Lubinsky <pace.lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) @state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>  
**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Marina Lamm <Marina.Lamm@USPTO.gov>; Kostelnik, Summer <Summer.Kostelnik@USPTO.GOV>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks- For Comment by Jan 23

Collin,

(b)(5)

(b)(5)

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(b)(5)

Our comments are explained in the attachment.

Thank you again for coordinating this

(b)(5)

(b)(5)

Karin

**From:** Weinberger, Collin (OS/OGA) (CTR) <Collin.Weinberger@hhs.gov>

**Sent:** Thursday, January 24, 2019 6:35 PM

**To:** Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <berkleyd@od.nih.gov>; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E]

<ccassetti@niaid.nih.gov>; CBC <CBC@bis.doc.gov>; Chacko, Betsie <betsie.chacko@HQ.DHS.GOV>; Coleman, Kimberly <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; Ferriter, Karin <Karin.Ferriter@USPTO.GOV>; (b)(6) @state.gov; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; Harrington, Conor B. EOP/USTR <Conor\_B\_Harrington@ustr.eop.gov>; Healey, Burke L - APHIS <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rzh7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI <srjamison@fbi.gov>; Jean-Paul Chretien <Jean-Paul\_Chretien@ostp.eop.gov>; Jodi Kouts <Jodi.Kouts@bis.doc.gov>; Jones, Franca R CDR USN DHA HEALTH SURV (US <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; Kishimori, Jennifer MCOL USARMY OSD HA (US <jennifer.m.kishimori.mil@mail.mil>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; Lamm, Marina <Marina.Lamm@USPTO.GOV>; Lane, Cliff (NIH/NIAID) [E] <clane@niaid.nih.gov>; Lashley-Johnson, Deborah <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil>; (b)(6) STATE.GOV; (b)(6) @state.gov; (b)(6) (STATE.GOV) (b)(6) @state.gov; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; Pace, Lubinsky@fas.usda.gov; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) STATE.GOV; (b)(6) @state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>; Tucker, Jessica (NIH/OD) [E] <jessica.tucker@nih.gov>; Wolinetz, Carrie (NIH/OD) [E] <carrie.wolinetz@nih.gov>; Jorgenson, Lyric (NIH/OD) [E] <lyric.jorgenson@nih.gov>; Ramkissoon, Kevin (NIH/OD) [C] <kevin.ramkissoon@nih.gov>

**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Dear Colleagues,

Thank you all for your comments and suggested edits to the WHO Code of Conduct for Pathogen Genetic Sequence Data During Outbreaks document. Before submitting the document tomorrow to WHO around COB, I wanted to share the compiled comments in the attached for everyone's review. I will be going through and removing duplicate comments as well as tomorrow, but wanted to provide time for your review should you be interested in doing so.

Please note that State has included two questions for NIH and USPTO in their comments (the questions are included as comment bubbles in the attached document).

While I have included a column that lists the Department/Agency from which each suggested edit/comment originated, I will be striking this column from the version we submit to WHO, so the comments will not be attributed to individual D/As. I will, however give them the overall list of D/As that submitted comments so they can have a sense of the breadth of expertise/perspectives represented by the comments.

Please also note that although the WHO webpage of the public consultation for this document says submitted comments may be posted publicly, we have asked that WHO not post USG comments publicly to allow our more detailed feedback, which they have agreed to oblige.

Best Regards,

Collin

Collin Weinberger, MPH

Senior Global Health Officer, Office of Pandemics and Emerging Threats

Futrend Technology, Inc (contractor)

Office of Global Affairs

U.S. Department of Health and Human Services

(O): (202) (b)(6) (M): (202) (b)(6)

[collin.weinberger@hhs.gov](mailto:collin.weinberger@hhs.gov)

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**From:** Weinberger, Collin (OS/OGA) (CTR)

**Sent:** Tuesday, January 22, 2019 9:50 AM

**To:** Balliram, Richard (OS/ASPR/SPPR) <[Richard.Balliram@hhs.gov](mailto:Richard.Balliram@hhs.gov)>; Barna, Lauren (OS/ASPR/SPPR) <[Lauren.Barna@hhs.gov](mailto:Lauren.Barna@hhs.gov)>; 'Bavari, Sina CIV USARMY MEDCOM USAMRIID (US' <[sina.bavari.civ@mail.mil](mailto:sina.bavari.civ@mail.mil)>; Bell, Tammie Jo (CDER) (FDA/CDER) <[Tammie.Bell2@fda.hhs.gov](mailto:Tammie.Bell2@fda.hhs.gov)>; Berkley, Dale (NIH/OD) [E] <[BerkleyD@OD.NIH.GOV](mailto:BerkleyD@OD.NIH.GOV)>; 'Beth.N.Harris@aphis.usda.gov' <[Beth.N.Harris@aphis.usda.gov](mailto:Beth.N.Harris@aphis.usda.gov)>; Blatner, Gretta (OS/ASPR/BARDA) <[Gretta.Blatner@hhs.gov](mailto:Gretta.Blatner@hhs.gov)>; Borio, Luciana (EOP.GOV) <[luciana.l.borio@nsc.eop.gov](mailto:luciana.l.borio@nsc.eop.gov)>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <[yfb0@cdc.gov](mailto:yfb0@cdc.gov)>; Bright, Rick (OS/ASPR/BARDA) <[Rick.Bright@hhs.gov](mailto:Rick.Bright@hhs.gov)>; Byrne, Patrick (OS/ASPR/ORM) <[Patrick.Byrne@hhs.gov](mailto:Patrick.Byrne@hhs.gov)>; Cassetti, Cristina (NIH/NIAID) [E] <[CCassetti@niaid.nih.gov](mailto:CCassetti@niaid.nih.gov)>; 'CBC' <[CBC@bis.doc.gov](mailto:CBC@bis.doc.gov)>; 'Chacko, Betsie' <[betsie.chacko@HQ.DHS.GOV](mailto:betsie.chacko@HQ.DHS.GOV)>; 'Coleman, Kimberly' <[kimberly.coleman@fema.dhs.gov](mailto:kimberly.coleman@fema.dhs.gov)>; Craig, Allen (CDC/DDID/NCIRD/OD) <[afc0@cdc.gov](mailto:afc0@cdc.gov)>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <[ivj7@cdc.gov](mailto:ivj7@cdc.gov)>; Disbrow, Gary (OS/ASPR/BARDA) <[Gary.Disbrow@hhs.gov](mailto:Gary.Disbrow@hhs.gov)>; Donis, Ruben (OS/ASPR/BARDA) <[Ruben.Donis@hhs.gov](mailto:Ruben.Donis@hhs.gov)>; Epstein, Jay (FDA/CBER) <[Jay.Epstein@fda.hhs.gov](mailto:Jay.Epstein@fda.hhs.gov)>; 'Ferriter, Karin' <[Karin.Ferriter@USPTO.GOV](mailto:Karin.Ferriter@USPTO.GOV)>; (b)(6) @state.gov <(b)(6)@state.gov>; Foster, Joseph (CDC/OCOO/OGC) <[jfb7@cdc.gov](mailto:jfb7@cdc.gov)>; 'Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US' <[cindy.k.fuchs.civ@mail.mil](mailto:cindy.k.fuchs.civ@mail.mil)>; Garcia, Mayra (FDA/CDRH) <[Mayra.Garcia@fda.hhs.gov](mailto:Mayra.Garcia@fda.hhs.gov)>; Handley, Gray (NIH/NIAID) [E] <[handleygr@niaid.nih.gov](mailto:handleygr@niaid.nih.gov)>; 'Harrington, Conor B. EOP/USTR' <[Conor\\_B\\_Harrington@ustr.eop.gov](mailto:Conor_B_Harrington@ustr.eop.gov)>; 'Healey, Burke L - APHIS' <[Burke.L.Healey@aphis.usda.gov](mailto:Burke.L.Healey@aphis.usda.gov)>; Helfand, Rita (CDC/DDID/NCEZID/OD) <[rz7@cdc.gov](mailto:rz7@cdc.gov)>; Higgs, Elizabeth (NIH/NIAID) [E] <[ehiggs@niaid.nih.gov](mailto:ehiggs@niaid.nih.gov)>; 'Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US' <[carl.c.holloway.civ@mail.mil](mailto:carl.c.holloway.civ@mail.mil)>; Horahan, Kevin (OS/ASPR/EMMO) <[Kevin.Horahan@hhs.gov](mailto:Kevin.Horahan@hhs.gov)>; Humes, Rosemary (OS/ASPR/BARDA) <[Rosemary.Humes@hhs.gov](mailto:Rosemary.Humes@hhs.gov)>; 'Ivan.Zapata@HQ.DHS.GOV' <[Ivan.Zapata@HQ.DHS.GOV](mailto:Ivan.Zapata@HQ.DHS.GOV)>; 'Jamison, Selwyn R. (WMD) (FBI)' <[srjamison@fbi.gov](mailto:srjamison@fbi.gov)>; 'Jean-Paul Chretien' <[Jean-Paul\\_Chretien@ostp.eop.gov](mailto:Jean-Paul_Chretien@ostp.eop.gov)>; 'Jodi Kouts' <[Jodi.Kouts@bis.doc.gov](mailto:Jodi.Kouts@bis.doc.gov)>; 'Jones, Franca R CDR USN DHA HEALTH SURV (US' <[franca.r.jones.mil@mail.mil](mailto:franca.r.jones.mil@mail.mil)>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <[vck3@cdc.gov](mailto:vck3@cdc.gov)>; 'Kishimori, Jennifer MCOL USARMY OSD HA (US' <[jennifer.m.kishimori.mil@mail.mil](mailto:jennifer.m.kishimori.mil@mail.mil)>; Krause, Philip (FDA/CBER) <[Philip.Krause@fda.hhs.gov](mailto:Philip.Krause@fda.hhs.gov)>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <[wdk1@cdc.gov](mailto:wdk1@cdc.gov)>; Lamana, Joseph (OS/ASPR/EMMO) <[Joseph.Lamana@hhs.gov](mailto:Joseph.Lamana@hhs.gov)>; 'Lamm, Marina' <[Marina.Lamm@USPTO.GOV](mailto:Marina.Lamm@USPTO.GOV)>; Lane, Cliff (NIH/NIAID) [E] <[CLANE@niaid.nih.gov](mailto:CLANE@niaid.nih.gov)>; 'Lashley-Johnson, Deborah' <[Deborah\\_E\\_Lashley-Johnson@ustr.eop.gov](mailto:Deborah_E_Lashley-Johnson@ustr.eop.gov)>; Lawrence, Theresa (OS/ASPR/SIIM) <[Theresa.Lawrence@HHS.GOV](mailto:Theresa.Lawrence@HHS.GOV)>; 'LeButt, Kimberly A CIV OSD OUSD ATL (US' <[kimberly.a.lebutt.civ@mail.mil](mailto:kimberly.a.lebutt.civ@mail.mil)>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; (b)(6) (STATE.GOV) <(b)(6)@state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <[Rebekka.Lueptow@hhs.gov](mailto:Rebekka.Lueptow@hhs.gov)>; Maher, Carmen (FDA/OC) <[Carmen.Maher@fda.hhs.gov](mailto:Carmen.Maher@fda.hhs.gov)>; Mair, Michael (FDA/OC) <[Michael.Mair@fda.hhs.gov](mailto:Michael.Mair@fda.hhs.gov)>; Marinissen, Maria

(OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; 'mcharris@usgs.gov' <mcharris@usgs.gov>; 'Moezie, Minna F.' <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; 'Ostlund, Eileen N - APHIS' <Eileen.N.Ostlund@aphis.usda.gov>; 'Pace.Lubinsky@fas.usda.gov' <Pace.Lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; 'Peter.D.Mamacos@nsc.eop.gov' <Peter.D.Mamacos@nsc.eop.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <MRanjan@niaid.nih.gov>; 'Robert L. Charles' <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; 'Schmitt, Beverly J - APHIS' <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6)@state.gov; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6)@state.gov; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US' <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <Joyelle.Dominique@nih.gov>; Eisenberg, Emily (CDC/OID/NCIRD) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/OID/NCIRD) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/OID/NCIRD) (dbj0@cdc.gov) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>  
Cc: Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; (b)(6)@state.gov (b)(6)@state.gov; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Dear Colleagues,

A friendly reminder to **please send any comments on the WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks by COB tomorrow, January 23rd** so that we can get a compiled set up USG comments back to WHO ahead of their deadline. I have reattached the document and comments form for convenience. Thank you to those of you who have already sent your comments.

Best Regards,  
Collin

<< File: GSDDraftCodeConduct\_forpublicconsultation-v1.pdf >> << File: WHO GSD code of conduct comment-form.docx >>

Collin Weinberger, MPH  
Senior Global Health Officer, Office of Pandemics and Emerging Threats  
Futrend Technology, Inc (contractor)  
Office of Global Affairs  
U.S. Department of Health and Human Services  
(O): (202) (b)(6) M: (202) (b)(6)  
collin.weinberger@hhs.gov

---

**From:** Weinberger, Collin (OS/OGA) (CTR)

**Sent:** Thursday, January 3, 2019 9:56 AM

**To:** Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; 'Bavari, Sina CIV USARMY MEDCOM USAMRIID (US' <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; 'Beth.N.Harris@aphis.usda.gov' <Beth.N.Harris@aphis.usda.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <CCassetti@niaid.nih.gov>; 'CBC'

<CBC@bis.doc.gov>; 'Chacko, Betsie' <betsie.chacko@HQ.DHS.GOV>; 'Coleman, Kimberly' <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; 'Ferriter, Karin' <Karin.Ferriter@USPTO.GOV>; (b)(6) @state.gov <(b)(6) @state.gov>; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; 'Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US' <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; 'Harrington, Conor B. EOP/USTR' <Conor\_B\_Harrington@ustr.eop.gov>; 'Healey, Burke L - APHIS' <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; 'Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US' <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; 'Ivan.Zapata@HQ.DHS.GOV' <Ivan.Zapata@HQ.DHS.GOV>; 'Jamison, Selwyn R. (WMD) (FBI' <srjamison@fbi.gov>; 'Jean-Paul Chretien' <Jean-Paul\_Chretien@ostp.eop.gov>; 'Jodi Kouts' <Jodi.Kouts@bis.doc.gov>; 'Jones, Franca R CDR USN DHA HEALTH SURV (US' <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; 'Kishimori, Jennifer MCOL USARMY OSD HA (US' <jennifer.m.kishimori.mil@mail.mil>; 'Korch, George (OS/ASPR/IO' <George.Korch@hhs.gov>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; 'Lamm, Marina' <Marina.Lamm@USPTO.GOV>; Lane, Cliff (NIH/NIAID) [E] <CLANE@niaid.nih.gov>; 'Lashley-Johnson, Deborah' <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SIIM) <Theresa.Lawrence@HHS.GOV>; 'LeButt, Kimberly A CIV OSD OUSD ATL (US' <kimberly.a.lebutt.civ@mail.mil>; (b)(6) (STATE.GOV) (b)(6) @state.gov <(b)(6) (STATE.GOV) (b)(6) @state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; 'mcharris@usgs.gov' <mcharris@usgs.gov>; 'Moezie, Minna F.' <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <z7q9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; 'Ostlund, Eileen N - APHIS' <Eileen.N.Ostlund@aphis.usda.gov>; 'Pace.Lubinsky@fas.usda.gov' <Pace.Lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; 'Peter.D.Mamacos@nsc.eop.gov' <Peter.D.Mamacos@nsc.eop.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <MRanjan@niaid.nih.gov>; 'Robert L. Charles' <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; 'Schmitt, Beverly J - APHIS' <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) (b)(6) @state.gov <(b)(6) @state.gov>; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) (STATE.GOV) (b)(6) @state.gov <(b)(6) @state.gov>; 'Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US' <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>

**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov <(b)(6) @state.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks- For Comment by Jan 23

Dear Colleagues,

WHO has released for comment its *draft code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease* (attached). WHO developed this under the umbrella of the R&D Blueprint and its data and sample sharing work, drawing from experiences during previous outbreaks where sharing of pathogen GSD has been delayed, thereby slowing outbreak and R&D responses. It also comes as WHO is in the process of a broader evaluation of its approach to data and sample sharing, and access and benefit sharing (ABS) as cross-cutting issues. We have been encouraging WHO to take leadership in assessing and explaining the public health impacts of sample sharing



and ABS, particularly the public health impacts of the Nagoya protocol, in alignment with our position that issues pertaining to public health should be determined by health experts.

Per WHO:

“Pathogen genetic sequence data (GSD) is an increasingly valuable source of information in understanding and controlling outbreaks of infectious disease. With the advent of next generation sequencing, the depth/extent of available information will expand further. A key concern in recent outbreaks has been variable timelines between the start of an outbreak and the public availability of the first and subsequent genetic sequences. WHO strongly supports public access to sequence data to inform public health and research decision-making during outbreaks, the equitable sharing of benefits derived from the use of such data, and the legitimate interests of data providers. WHO has consulted with many stakeholders and institutions working in the pathogen sequencing arena, including those who have been involved in applications to recent outbreaks. Based on these consultations, and on lessons learned from recent outbreaks as part of the data sharing workstream of the WHO R&D Blueprint, WHO is proposing elements of a code of conduct for GSD sharing in infectious disease outbreaks.

Through this code of conduct WHO seeks to contribute towards an enabling environment for sharing of pathogen GSD where equitable benefit sharing and the needs of data providers around the world can be addressed so that rapid international sharing of sequence data can occur consistently, in accord with IHR 2005, allowing public health authorities, product developers and researchers to collaborate more effectively from a position of mutual trust with respect for submitters’ rights to the information they provide.”

WHO is asking for stakeholders to provide comments via the attached comment form by January 28. **I would be happy to consolidate USG comments and send them all together in a single compiled document if you please send me your comments by COB Wednesday, January 23, 2019.**

If there are strong concerns around the document, we can organize a call in coordination with the leads of the USG Sample Sharing Working Group and our colleagues at State IHB to discuss our approach to providing feedback, perhaps considering drafting a summary document outlining our concerns as Ruvani suggested last week as opposed to simply providing comments via the comment form.

Best Regards,

Collin

<< File: GSDDraftCodeConduct\_forpublicconsultation-v1.pdf >> << File: WHO GSD code of conduct comment-form.docx >>

Collin Weinberger, MPH

Senior Global Health Officer, Office of Pandemics and Emerging Threats

Futrend Technology, Inc (contractor)

Office of Global Affairs

U.S. Department of Health and Human Services

(O): (202) (b)(6) (M): (202) (b)(6)

[collin.weinberger@hhs.gov](mailto:collin.weinberger@hhs.gov)

**From:** Ferriter, Karin [Karin.Ferriter@USPTO.GOV]  
**Sent:** 1/23/2019 11:19:59 AM  
**To:** Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Balliram, Richard (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84c90e08bde475889893cf95db919bf-HHS-Richard]; Barna, Lauren (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=271142eac37342bf97e640c7903bb7a1-HHS-Lauren.]; Bavari, Sina CIV USARMY MEDCOM USAMRIID (US [sina.bavari.civ@mail.mil]); Bell, Tammie Jo (CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb3d1b8803c245689b15a0c5cd9cd625-Tammie.Bell]; Berkley, Dale D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2ec3b9be3cc4903a272d25d47ebfb6a-HHS-Berkley]; Beth.N.Harris@aphis.usda.gov; Blatner, Gretta L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecc23ddcb3c54d448c98b00895a60011-HHS-Gretta.]; Borio, Luciana (EOP.GOV) [luciana.l.borio@nsc.eop.gov]; Brand, Kevin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=980d7ad635e74ede97d34dff3761cf3-HHS-yfb0-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Byrne, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41360f61e1ed49729739326ccbe6eea0-HHS-Patrick]; Cassetti, Cristina G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5a44e839c5642abb30e10feb69800b4-HHS-CCasset]; CBC [CBC@bis.doc.gov]; Chacko, Betsie [betsie.chacko@HQ.DHS.GOV]; Coleman, Kimberly [kimberly.coleman@fema.dhs.gov]; Craig, Allen (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=258003fd08cc4d1ba85dc4e70ec3b708-HHS-afc0-cd]; Degruy, Glen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ed115fe668741ae84d51c212ec00d0d-HHS-ivj7-cd]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Epstein, Jay [Jay.Epstein@state.gov]; Foster, Joseph A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b88c70a10f1843c49dafb981ae48f09c-HHS-jbf7-cd]; Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US [cindy.k.fuchs.civ@mail.mil]); Garcia, Mayra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7db05677732d4023bcd772ee0474055-GarciaM]; Handley, Gray G (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c028db015f1f4544ab4c265ec05ad834-HHS-handley]; Harrington, Conor B. EOP/USTR [Conor\_B\_Harrington@ustr.eop.gov]; Healey, Burke L - APHIS [Burke.L.Healey@aphis.usda.gov]; Helfand, Rita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae435981a2b14a1d8b16cfd4c954575f-HHS-rzh7-cd]; Higgs, Elizabeth S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ac36dd643c04994b3161baf825cbfc3-HHS-ehiggs-]; Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US [carl.c.holloway.civ@mail.mil]); Horahan, Kevin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ebbbca24c1e47ac888dea10afb73063-HHS-Kevin.H]; Humes, Rosemary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de8a41cc8d5da69787255ca964affa-HHS-Rosemar]; Ivan.Zapata@HQ.DHS.GOV; Jamison, Selwyn R. (WMD) (FBI [srjamison@fbi.gov]; Jean-Paul Chretien [Jean-Paul\_Chretien@ostp.eop.gov]; Jodi Kouts [Jodi.Kouts@bis.doc.gov]; Jones, Franca R CDR USN DHA HEALTH SURV (US [franca.r.jones.mil@mail.mil]); Kapil, Vikas (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b24fd89e78a64022875d565407d5c30a-HHS-vck3-cd]; Kishimori, Jennifer M COL USARMY OSD HA (US [jennifer.m.kishimori.mil@mail.mil]); Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Kuhnert-Tallman, Wendi L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f8ee10758c4677b417de6b7c8ec5b5-HHS-wdk1-cd]; Lamana, Joseph P

(OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9608ab2ee87f4b79ba753036e3d1f3e7-HHS-Joseph.]; Lamm, Marina [Marina.Lamm@USPTO.GOV]; Lane, Henry C (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d904337536cf41719032a9359a1ec2ab-HHS-CLANE-n]; Lashley-Johnson, Deborah [Deborah\_E\_Lashley-Johnson@ustr.eop.gov]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; LeButt, Kimberly A CIV OSD OUSD ATL (US [kimberly.a.lebutt.civ@mail.mil]; (b)(6) (STATE.GOV) (b)(6)@state.gov]; (b)(6) (STATE.GOV) (b)(6)@state.gov]; Lueptow, Rebekka (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=944f0156dbf64ffa95cc785bb56ca0f-HHS-Rebekka]; Maher, Carmen (FDA/OC) [Carmen.Maher@fda.hhs.gov]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Marinissen, Maria Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bad48dfabf84875995b2cad6a6bf46f-HHS-Maria.M]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; mcharris@usgs.gov; Moezie, Minna F. [Minna.Moezie@USPTO.GOV]; Montgomery, Joel M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b678cd2c99643de9200e8b0a1e4fd44-HHS-ztq9-cd]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Mowatt, Michael R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=11dc291d9bdc423e8746678733154767-HHS-MMOWATT]; Music, Francesca (MIL) [francesca.c.music2.civ@mail.mil]; Ostlund, Eileen N - APHIS [Eileen.N.Ostlund@aphis.usda.gov]; Pace.Lubinsky@fas.usda.gov; Pallansch, Mark (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2941652b4c784575b079ef1164b4f089-HHS-map1-cd]; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Puglielli, Maryann T (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=419865c4977045fbb9eb9ac500edc207-HHS-maryann]; Ranjan, Mukul (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40fa81127c2042fa913539af005560d6-HHS-MRanjan]; Robert L. Charles [robert.l.charles4.civ@mail.mil]; Sanchez, Angela J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=267c51760e9b4c2298df48de8967a08a-HHS-amj4-cd]; Schafer, Julie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad453f0426b24a52bef9d08e1fef7967-HHS-Julie.S]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Schmitt, Beverly J - APHIS [Beverly.J.Schmitt@aphis.usda.gov]; (b)(6)@state.gov]; Shaw, Michael W (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ddc530330f74747b3b7f47e36c4c778-HHS-mws2-cd]; Sherman, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cac01b38636f4165b03a0fbb18bba1c9-HHS-Susan.S]; Shope, Suzanne (CDC/OD/OADS) [awd8@cdc.gov]; Stewart, Jessica L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ddbada5915de4419eacb96dfdd49e4687-HHS-Jessica]; (b)(6) (STATE.GOV) (b)(6)@state.gov]; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US [robert.g.ulrich.civ@mail.mil]; Villanueva, Julie M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c94d2e2894444227ae6fec6c226cc55b-HHS-jfv3-cd]; Vinter, Serena (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=994f0f1af6d6491fae1d0788b3667454-HHS-uvv3-cd]; Dominique, Joyelle K (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c948ff2734604738b1e1f739a594902c-HHS-joyelle]; Eisenberg Lobelo, Emily (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729fffd5a474613a4e00af6cad651ad-HHS-idq5-cd]; Greene, Carolyn M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5593b7cf42a472096db48fb69f81c85-HHS-cqg4-cd]; Katz, Jacqueline M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e8bf32a5224c5faa0b2a8c208b31e0-HHS-jmk9-cd]; Jernigan, Daniel B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group



(OS/ASPR/SPPR) <Theresa.Lawrence@HHS.GOV>; LeButt, Kimberly A CIV OSD OUSD ATL (US <kimberly.a.lebutt.civ@mail.mil> (b)(6) STATE.GOV (b)(6) @state.gov> (b)(6) STATE.GOV (b)(6) @state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; mcharris@usgs.gov; Moezie, Minna F. <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <ztq9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <mmowatt@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; Ostlund, Eileen N - APHIS <Eileen.N.Ostlund@aphis.usda.gov>; Pace, Lubinsky@fas.usda.gov; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; Peter.D.Mamacos@nsc.eop.gov; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <mranjan@niaid.nih.gov>; Robert L. Charles <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; Schmitt, Beverly J - APHIS <Beverly.J.Schmitt@aphis.usda.gov>; (b)(6) @state.gov>; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; (b)(6) STATE.GOV (b)(6) @state.gov>; Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSS/CGH/OD) <uvv3@cdc.gov>; Dominique, Joyelle (NIH/NIAID) [E] <joyelle.dominique@nih.gov>; Eisenberg, Emily (CDC/DDID/NCIRD/ID) <idq5@cdc.gov>; Greene, Carolyn M. (CDC/DDID/NCIRD/ID) <cqg4@cdc.gov>; Katz, Jackie M. (CDC/DDID/NCIRD/ID) <jmk9@cdc.gov>; Jernigan, Daniel B. (CDC/DDID/NCIRD/ID) <dbj0@cdc.gov>; Galloway, Summer (CDC/DDID/NCIRD/ID) (CTR) <nmd3@cdc.gov>  
**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; (b)(6) @state.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** RE: WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Dear Colleagues,

A friendly reminder to **please send any comments on the WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks by COB tomorrow, January 23rd** so that we can get a compiled set up USG comments back to WHO ahead of their deadline. I have reattached the document and comments form for convenience. Thank you to those of you who have already sent your comments.

Best Regards,  
Collin

Collin Weinberger, MPH  
Senior Global Health Officer, Office of Pandemics and Emerging Threats  
Futrend Technology, Inc (contractor)  
Office of Global Affairs  
U.S. Department of Health and Human Services  
(O): (202) (b)(6) (M): (202) (b)(6)  
[collin.weinberger@hhs.gov](mailto:collin.weinberger@hhs.gov)

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**From:** Weinberger, Collin (OS/OGA) (CTR)

**Sent:** Thursday, January 3, 2019 9:56 AM

**To:** Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Barna, Lauren (OS/ASPR/SPPR) <Lauren.Barna@hhs.gov>; 'Bavari, Sina CIV USARMY MEDCOM USAMRIID (US' <sina.bavari.civ@mail.mil>; Bell, Tammie Jo (CDER) (FDA/CDER) <Tammie.Bell2@fda.hhs.gov>; Berkley, Dale (NIH/OD) [E] <BerkleyD@OD.NIH.GOV>; 'Beth.N.Harris@aphis.usda.gov' <Beth.N.Harris@aphis.usda.gov>; Blatner, Gretta (OS/ASPR/BARDA) <Gretta.Blatner@hhs.gov>; Borio, Luciana (EOP.GOV) <luciana.l.borio@nsc.eop.gov>; Brand, Kevin (CDC/DDPHSS/OS/OTI) <yfb0@cdc.gov>; Bright, Rick (OS/ASPR/BARDA) <Rick.Bright@hhs.gov>; Byrne, Patrick (OS/ASPR/ORM) <Patrick.Byrne@hhs.gov>; Cassetti, Cristina (NIH/NIAID) [E] <CCassetti@niaid.nih.gov>; 'CBC'

<CBC@bis.doc.gov>; 'Chacko, Betsie' <betsie.chacko@HQ.DHS.GOV>; 'Coleman, Kimberly' <kimberly.coleman@fema.dhs.gov>; Craig, Allen (CDC/DDID/NCIRD/OD) <afc0@cdc.gov>; Degruy, Glen A. (CDC/DDPHSIS/CPR/DSAT) <ivj7@cdc.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Donis, Ruben (OS/ASPR/BARDA) <Ruben.Donis@hhs.gov>; Epstein, Jay (FDA/CBER) <Jay.Epstein@fda.hhs.gov>; 'Ferriter, Karin' <Karin.Ferriter@USPTO.GOV>; '(b)(6)'@state.gov' '(b)(6)'@state.gov'; Foster, Joseph (CDC/OCOO/OGC) <jbf7@cdc.gov>; 'Fuchs, Cindy K CIV USARMY MEDCOM USAMRIID (US' <cindy.k.fuchs.civ@mail.mil>; Garcia, Mayra (FDA/CDRH) <Mayra.Garcia@fda.hhs.gov>; Handley, Gray (NIH/NIAID) [E] <handleygr@niaid.nih.gov>; 'Harrington, Conor B. EOP/USTR' <Conor\_B\_Harrington@ustr.eop.gov>; 'Healey, Burke L - APHIS' <Burke.L.Healey@aphis.usda.gov>; Helfand, Rita (CDC/DDID/NCEZID/OD) <rz7@cdc.gov>; Higgs, Elizabeth (NIH/NIAID) [E] <ehiggs@niaid.nih.gov>; 'Holloway, Carl C (Clay) CIV USARMY DOD JPEOCBD (US' <carl.c.holloway.civ@mail.mil>; Horahan, Kevin (OS/ASPR/EMMO) <Kevin.Horahan@hhs.gov>; Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>; 'Ivan.Zapata@HQ.DHS.GOV' <Ivan.Zapata@HQ.DHS.GOV>; 'Jamison, Selwyn R. (WMD) (FBI' <srjamison@fbi.gov>; 'Jean-Paul Chretien' <Jean-Paul\_Chretien@ostp.eop.gov>; 'Jodi Kouts' <Jodi.Kouts@bis.doc.gov>; 'Jones, Franca R CDR USN DHA HEALTH SURV (US' <franca.r.jones.mil@mail.mil>; Kapil, Vikas (CDC/DDPHSIS/CGH/OD) <vck3@cdc.gov>; 'Kishimori, Jennifer MCOL USARMY OSD HA (US' <jennifer.m.kishimori.mil@mail.mil>; 'Korch, George (OS/ASPR/IO' <George.Korch@hhs.gov>; Krause, Philip (FDA/CBER) <Philip.Krause@fda.hhs.gov>; Kuhnert-Tallman, Wendi (CDC/DDID/NCEZID/OD) <wdk1@cdc.gov>; Lamana, Joseph (OS/ASPR/EMMO) <Joseph.Lamana@hhs.gov>; 'Lamm, Marina' <Marina.Lamm@USPTO.GOV>; Lane, Cliff (NIH/NIAID) [E] <CLANE@niaid.nih.gov>; 'Lashley-Johnson, Deborah' <Deborah\_E\_Lashley-Johnson@ustr.eop.gov>; Lawrence, Theresa (OS/ASPR/SIIM) <Theresa.Lawrence@HHS.GOV>; 'LeButt, Kimberly A CIV OSD OUSD ATL (US' <kimberly.a.lebutt.civ@mail.mil>; '(b)(6)' (STATE.GOV) <(b)(6)'@state.gov>; '(b)(6)' (STATE.GOV) <(b)(6)'@state.gov>; Lueptow, Rebekka (OS/ASPR/BARDA) <Rebekka.Lueptow@hhs.gov>; Maher, Carmen (FDA/OC) <Carmen.Maher@fda.hhs.gov>; Mair, Michael (FDA/OC) <Michael.Mair@fda.hhs.gov>; Marinissen, Maria (OS/ASPR/SPPR) <Maria.Marinissen@hhs.gov>; Marston, Hilary (NIH/NIAID) [E] <hilary.marston@nih.gov>; 'mcharris@usgs.gov' <mcharris@usgs.gov>; 'Moezie, Minna F.' <Minna.Moezie@USPTO.GOV>; Montgomery, Joel M. (CDC/DDID/NCEZID/OD) <z7q9@cdc.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; Mowatt, Michael (NIH/NIAID) [E] <MMOWATT@niaid.nih.gov>; Music, Francesca (MIL) <francesca.c.music2.civ@mail.mil>; 'Ostlund, Eileen N - APHIS' <Eileen.N.Ostlund@aphis.usda.gov>; 'Pace.Lubinsky@fas.usda.gov' <Pace.Lubinsky@fas.usda.gov>; Pallansch, Mark A. (CDC/DDID/NCIRD/DVD) <map1@cdc.gov>; 'Peter.D.Mamacos@nsc.eop.gov' <Peter.D.Mamacos@nsc.eop.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Puglielli, Maryann (NIH/NIAID) [E] <maryann.puglielli@nih.gov>; Ranjan, Mukul (NIH/NIAID) [E] <MRanjan@niaid.nih.gov>; 'Robert L. Charles' <robert.l.charles4.civ@mail.mil>; Sanchez, Angela J. (CDC/DDPHSS/OS/OTI) <amj4@cdc.gov>; Schafer, Julie (OS/ASPR/BARDA) <Julie.Schafer@hhs.gov>; Scherf, Uwe (FDA/CDRH) <Uwe.Scherf@fda.hhs.gov>; 'Schmitt, Beverly J - APHIS' <Beverly.J.Schmitt@aphis.usda.gov>; '(b)(6)' <(b)(6)'@state.gov>; Shaw, Michael (CDC/DDID/OD) <mws2@cdc.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Shope, Suzanne (CDC/OD/OADS) <awd8@cdc.gov>; Stewart, Jessica L. (HHS/OS/OGA) <Jessica.Stewart@hhs.gov>; '(b)(6)' (STATE.GOV) <(b)(6)'@state.gov>; 'Ulrich, Robert G CIV USARMY MEDCOM USAMRIID (US' <robert.g.ulrich.civ@mail.mil>; Villanueva, Julie M. (CDC/DDID/NCEZID/DPEI) <jfv3@cdc.gov>; Vinter, Serena (CDC/DDPHSIS/CGH/OD) <uvv3@cdc.gov>;

**Cc:** Ferrey, Seth (OS/OGA) <Seth.Ferrey@hhs.gov>; Yu, Anne (HHS/OS/OGA) <Anne.Yu@hhs.gov>; Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>; '(b)(6)' <(b)(6)'@state.gov>; '(b)(6)' <(b)(6)'@state.gov>; Chandrasekera, Ruvani (OS/ASPR/SPPR) <Ruvani.Chandrasekera@hhs.gov>

**Subject:** WHO Code of Conduct Pathogen Genetic Sequence Data During Outbreaks - For Comment by Jan 23

Dear Colleagues,

WHO has released for comment its *draft code of conduct for open and timely sharing of pathogen genetic sequence data during outbreaks of infectious disease* (attached). WHO developed this under the umbrella of the R&D Blueprint and its data and sample sharing work, drawing from experiences during previous outbreaks where sharing of pathogen GSD has been delayed, thereby slowing outbreak and R&D responses. It also comes as WHO is in the process of a broader evaluation of its approach to data and sample sharing, and access and benefit sharing (ABS) as cross-cutting issues. We have been encouraging WHO to take leadership in assessing and explaining the public health impacts of sample sharing

and ABS, particularly the public health impacts of the Nagoya protocol, in alignment with our position that issues pertaining to public health should be determined by health experts.

Per WHO:

“Pathogen genetic sequence data (GSD) is an increasingly valuable source of information in understanding and controlling outbreaks of infectious disease. With the advent of next generation sequencing, the depth/extent of available information will expand further. A key concern in recent outbreaks has been variable timelines between the start of an outbreak and the public availability of the first and subsequent genetic sequences. WHO strongly supports public access to sequence data to inform public health and research decision-making during outbreaks, the equitable sharing of benefits derived from the use of such data, and the legitimate interests of data providers. WHO has consulted with many stakeholders and institutions working in the pathogen sequencing arena, including those who have been involved in applications to recent outbreaks. Based on these consultations, and on lessons learned from recent outbreaks as part of the data sharing workstream of the WHO R&D Blueprint, WHO is proposing elements of a code of conduct for GSD sharing in infectious disease outbreaks.

Through this code of conduct WHO seeks to contribute towards an enabling environment for sharing of pathogen GSD where equitable benefit sharing and the needs of data providers around the world can be addressed so that rapid international sharing of sequence data can occur consistently, in accord with IHR 2005, allowing public health authorities, product developers and researchers to collaborate more effectively from a position of mutual trust with respect for submitters’ rights to the information they provide.”

WHO is asking for stakeholders to provide comments via the attached comment form by January 28. **I would be happy to consolidate USG comments and send them all together in a single compiled document if you please send me your comments by COB Wednesday, January 23, 2019.**

If there are strong concerns around the document, we can organize a call in coordination with the leads of the USG Sample Sharing Working Group and our colleagues at State IHB to discuss our approach to providing feedback, perhaps considering drafting a summary document outlining our concerns as Ruvani suggested last week as opposed to simply providing comments via the comment form.

Best Regards,

Collin

<< File: GSDDraftCodeConduct\_forpublicconsultation-v1.pdf >> << File: WHO GSD code of conduct comment-form.docx >>

Collin Weinberger, MPH

Senior Global Health Officer, Office of Pandemics and Emerging Threats

Futrend Technology, Inc (contractor)

Office of Global Affairs

U.S. Department of Health and Human Services

(O): (202) (b)(6) (M): (202) (b)(6)

[collin.weinberger@hhs.gov](mailto:collin.weinberger@hhs.gov)

**(b)(5)**



**(b)(5)**

**(b)(5)**

CL-2022-00059 B-00000966682 "UNCLASSIFIED" 8/28/2022  
**From:** Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]  
**Sent:** 2/25/2021 6:33:15 AM  
**To:** Blair, Joan W. (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8cc3d088be164491a76b9ce048d71a02-BLAIR]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]  
**CC:** Badoo, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d025eab2aa14f8f83e7dd5510e7f578-Badoo]; Limoli, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bdfe247f00604c6dbf1e16d4ddc1c285-MLimoli]  
**Subject:** RE: [EXTERNAL] UK Vaccine Narrative Assessment 19 February 2021

Dear Joan,

Thanks for forwarding these along.

Best Regards,  
Peter

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**From:** Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>  
**Sent:** Thursday, February 25, 2021 5:24 AM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>  
**Cc:** Badoo, Judith <Judith.Badoo@fda.hhs.gov>; Limoli, Michelle <Michelle.Limoli@fda.hhs.gov>  
**Subject:** FW: [EXTERNAL] UK Vaccine Narrative Assessment 19 February 2021

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**From:** Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>  
**Sent:** Thursday, February 25, 2021 3:57 AM  
**To:** Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Scherer, Matthew <Matthew.Scherer@fda.hhs.gov>; Louati, Claudia (FSN)\* <Claudia.Louati@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>  
**Subject:** FW: [EXTERNAL] UK Vaccine Narrative Assessment 19 February 2021

FYI

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**From:** (b) (6) @state.gov  
**Sent:** Thursday, February 25, 2021 1:06 AM  
**To:** GFC-Russia Team <(b) (6) @state.gov>; (b) (6) @state.gov; (b) (6) @state.gov; (b) (6) @state.gov; (b) (6) @usaid.gov; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>  
**Cc:** (b) (6) @state.gov; (b) (6) @state.gov  
**Sub** [EXTERNAL] UK Vaccine Narrative Assessment 19 February 2021

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear colleagues,

Please see attached last week's UK assessment of Russian and Chinese vaccine narratives. Please do not share this report outside of the USG.

Classified by DAS, A/GIS on 5/6/2022 - Class: CONFIDENTIAL - Reason: 1.4(b), 1.4(d) - Declassify on: 5/6/2032

FDA-CBER-2020-5341-0008123

(b)(1)

Best regards,

(b) (6)

Counter Disinformation Officer- Russia Team

Global Engagement Center

United States Department of State

Muscogee International | Contractor

Teleworking cell: (b) (6)

(b) (6) [state.gov](#)



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**From:** Rouse, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=185BAE767862490D88EDA44DB74A75B3-ROUSED]  
**Sent:** 1/22/2021 1:39:50 PM  
**To:** Osorio, Manuel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=66e68e9cbce448f28184c7cb5f5154a0-Osorio]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Devore, Nicolette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd9d011e02c45d6b1005d46342cad69-Devore]  
**Subject:** RE: UK Vaccine Narrative Assessment 22 January 2021

According to our FORMER President Russia would never do anything like that. Putin promised.

---

**From:** Osorio, Manuel <Manuel.Osorio@fda.hhs.gov>  
**Sent:** Friday, January 22, 2021 12:59 PM  
**To:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>  
**Subject:** RE: UK Vaccine Narrative Assessment 22 January 2021

Any guesses on which nation state manipulated the hacked EMA internal documents?

Hmmm, let me think about it for half a second....

M

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**From:** Cho, David S (CBER) <David.Cho@fda.hhs.gov>  
**Sent:** Friday, January 22, 2021 12:52 PM  
**To:** Rouse, David <David.Rouse@fda.hhs.gov>; Devore, Nicolette <Nicolette.Devore@fda.hhs.gov>; Osorio, Manuel <Manuel.Osorio@fda.hhs.gov>  
**Subject:** FW: UK Vaccine Narrative Assessment 22 January 2021

FYI.

---

**From:** Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>  
**Sent:** Friday, January 22, 2021 12:49 PM  
**To:** Marks, Peter <Peter.Marks@fda.hhs.gov>; Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>  
**Subject:** Fwd: UK Vaccine Narrative Assessment 22 January 2021

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**From:** Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>  
**Sent:** Friday, January 22, 2021 12:35 PM  
**To:** Kweder, Sandra L; Nalubola, Ritu; Blair, Joan W. (CBER); Ross, Bruce  
**Subject:** RE: UK Vaccine Narrative Assessment 22 January 2021

Agree.

---

**From:** Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>  
**Sent:** Friday, January 22, 2021 12:34 PM

To: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>  
CL-2022 00059 E-00000966192 "UNCLASSIFIED" 07/28/2022

Subject: RE: UK Vaccine Narrative Assessment 22 January 2021

Just insane.

From: Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>

Sent: Friday, January 22, 2021 6:18 PM

To: Kweder, Sandra L <Sandra.Kweder@fda.hhs.gov>; Blair, Joan W. (CBER) <Joan.Blair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>

Subject: FW: UK Vaccine Narrative Assessment 22 January 2021

FYI bit troubling.

From (b) (6) @state.gov>

Sent: Friday, January 22, 2021 5:58 PM

To: GEC-Russia Team (b) (6)

(b) (6) @state. ov>; (b) (6) state. ov>;

(b) (6)

(b) (6) usaid. ov>; Nalubola, Ritu <Ritu.Nalubola@fda.hhs.gov>

Subject: UK Vaccine Narrative Assessment 22 January 2021

Dear colleagues,

Please see attached this week's UK assessment of Russian and Chinese vaccine narratives. Please do not share this report outside of the USG.

(b)(1)

(b)(1)

Best regards,

(b) (6)

Counter Disinformation Officer- Russia Team

Global Engagement Center

United States Department of State

Muscogee International | Contractor

Teleworking cell: (b) (6)

(b) (6) [@state.gov](#)

