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From:
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To:
Virginia Legislature, in favor of HB102, Rep Greenhalgh

Use of FDA approved drugs for off label purposes is a time-honored tradition and practice specifically allowed by the FDA, which makes this clear in their own publications. Never have I seen mutual consent off-label prescription condemned, until COVID-19.

Many drugs we use routinely are not officially FDA approved for the purpose. E.g. haloperidol has been used for decades for agitation in critically ill patients, but it was never tested and studied for this by the FDA, and it has never been approved by the FDA for that purpose. It affects certain neurotransmitter transduction and has a favorable clinical effect, and many decades of use have shown it to be safe when proper precautions are taken.

At one point, when newer drugs became available that could replace or substitute for haloperidol, a spate of literature came out condemning the use of this old drug. But experience has shown that these newer drugs are less easy to use and titrate, and carry the same theoretical risks. Furthermore, they are ALSO not FDA approved for the purpose in which they are routinely used in intensive care, AND, even more striking, they carry BLACK BOX WARNINGS against their very use.

* For example, the drug quetiapine (Seroquel) is FDA approved (i.e., “indicated”) only for certain mental/mood conditions, including schizophrenia, bipolar disorder, and sudden episodes of mania or depression associated with bipolar disorder. Not only is there no FDA indication for its use in intensive care, but the drug carries the following BLACK BOX WARNING that alludes to its CONTRAINDICATION in the very group in which it is used most frequently. And yet, no pharmacist I have ever encountered refuses to dispense it in the hospital. Never, not once have I received pushback upon the prescription of quetiapine in the hospital, nor have I seen any other physician receive such pushback.

** BLACK-BOX WARNING: Increased Mortality in Elderly Patients with Dementia-Related Psychosis… SEROQUEL (quetiapine) is not approved for the treatment of patients with Dementia-Related Psychosis. **

I simply wish to emphasize to the Virginia legislature that the arbitrary practice of refusing to allow the use of certain drugs that maintain similar safety profiles to the ones I have described has never occurred in my experience during my career, until the time of COVID-19. I will refrain here from any speculation as to why this should be, but the legislature should understand that there is no legitimate reason for it. Arguments against such a drug’s use for “lack of evidence” are specious and vacuous. A great many things are done for patients at much greater expense and at much greater risk than prescribing a drug with decades of safety data, and yet these things are also not specifically approved, nor questioned by pharmacists or administrators. Current climate in major US hospitals that now routinely prohibits the exercise of autonomous physician judgment in concert with full patient disclosure, assent, and deliberate consent is so peculiar, I have no words to describe it. It is as though physicians were suddenly told they were being disallowed from using their stethoscopes, upon pain of administrative sanction for doing so. After all, has the practice ever been FDA approved? Is such use

better than performing an echocardiogram? Is the practice standardized and routinely assessed for competency? I will be happy to entertain questioning and to elaborate in person.