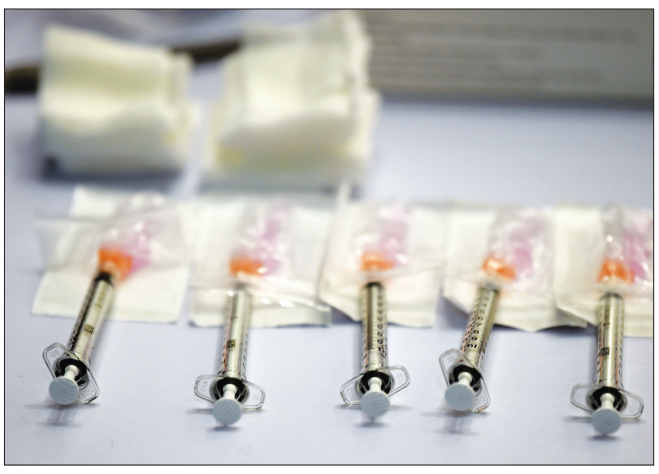
Why hasn't FDA given full approval for COVID vaccines?

By TOM AVRIL
The Philadelphia Inquirer

More than eight months ago, large studies found that both the Pfizer-BioNTech and Moderna COVID-19 vaccines reduced the risk of illness by more than 90%. Yet the U.S. Food and Drug Administration has not yet granted them full approval, to the dismay of public-health officials eager to boost vaccination rates as the delta variant sends infections skyward.



Brad Horrigan/The Hartford Courant-TNS

Doses of the Moderna COVID-19 vaccine.

So what is the holdup?

Part of the reason, according to experts in drug regulation, may be simply that the agency can afford to take the time.

In December, the FDA authorized the first two vaccines for emergency use, and did so for a third in February. Those authorizations, though based on extensive, rigorous research, are temporary in nature. Before granting permanent approval ("licensure"), the agency can spend months to make triply sure that all regulatory requirements are met, given that the vaccines are available for all who want them in the meantime.

Still, with the emergence of the highly transmissible delta variant of the coronavirus, public-health officials are eager for the agency to move forward, contending that full approval may pave the way for more people to be vaccinated.

That could happen in two ways. Physicians hope that if the agency licenses the drugs, some who are hesitant about vaccination may become more receptive. Even if not, more businesses and institutions may decide they have a legal basis for requiring the shots, said Greer Donley, an assistant professor at the University of Pittsburgh Law School.

Hundreds of universities already have instituted vaccine mandates for students enrolling this fall, in one case surviving a challenge in federal court. And on Monday, the U.S. Department of Veterans Affairs announced it would require the shots for 115,000 frontline medical workers. But with full approval, Donley said, employers seeking to require the vaccines may feel they are on even firmer legal ground.

Either way, FDA's career civil servants, accustomed to carrying out their careful reviews in relative obscurity, are under public pressure like never before.

What is emergency use?

The FDA's power to authorize drugs for emergency use is relatively new, enacted by Congress in 2004 in response to the anthrax attacks of 2001.

The agency can grant such an approval if it is "reasonable to believe" that the product may be effective, and that its "known and potential benefits" exceed its "known and potential risks," according to the statute.

But vaccines are not like most drugs, in that they are administered to healthy people to prevent illness, not to treat it. So when the FDA issued guidance on what it would require before authorizing vaccines against COVID-19, the agency went beyond the letter of the law.

Drug makers learned they would need to enroll tens of thousands of participants, randomly assigning some to receive the vaccine and others to get a placebo. In short, they needed to run the type of large, well controlled trial that is required for regular approval of any vaccine, said biostatistician Susan S. Ellenberg, a professor emerita at the University of Pennsylvania's Perelman School of Medicine.

On Nov. 9, the partnership of Pfizer and BioNTech announced that its vaccine prevented more than 90% of cases of COVID-19, far exceeding most expectations.

Similar results came a week later from Moderna Inc., and by the middle of December, the FDA had authorized emergency use of both.

What more do they need?

Before granting the emergency authorizations, the FDA analyzed the rates of any side effects for two months following administration of the vaccines.

Any side effects caused by vaccines tend to arise within a month, and physicians generally agreed that two months' of safety data was more than sufficient — especially given the urgency of curbing the pandemic during the wintertime surge.

The evidence on the COVID-19 vaccines was promising, with some participants reporting temporary consequences such as a fever, headache, or sore arm — nothing serious or long-lasting.

110 Announcements

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110 Announcements

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SATURDAY, JULY 31, 2021

CROSSWORD PUZZLER

ACROSS

1 Swamp swimmer
6 Egg producer
9 Gleeful cry
12 Playing marble
13 Christina's pop
14 Turn down
15 Champagne glass
16 Fragrant stick
18 Coxcomb
19 Bell-shaped flowers
21 Bleaters
23 Gaze at
24 Litter members
28 Sour
30 Big green parrot
31 Daughters' cousins
34 UFO crew
37 Augment
38 Spotted, as a horse
39 Pedestal
41 Put under wraps
42 Outbuilding
46 Ethically neutral
49 Fiesta cheer
50 Red powdery condiment
53 Over
55 Some whiskey
56 Tolerate
57 Inventor
58 Hedge shrub
59 Hole in a needle
60 Out of style

DOWN

1 Faux pas
2 Softly lit
3 Hosiery shade
4 Homer-hitter Mel
5 Lurch
6 Flagged down
7 Baseball's — Banks
8 — and easy
9 Abby's sister
10 Man's pronoun
11 Logging tool
17 Telepathy
20 Osiris' beloved
22 Marsupial pocket
25 HI guitar
26 Writing implement
27 Airline to Stockholm
29 After yr. 1
31 Apprehend
32 NW state
33 Koch and Wynn
34 Verdi princess
35 French article
36 Analyst's concerns
38 Steal software
40 Keep an — to the ground
41 Mawkish
43 Latches
44 Goblins
45 Steel plow inventor
47 Marathon unit
48 Reading aid
50 Apply a jimmy
51 Affirmative
52 Seat on the aisle
54 Bleat

Answer to Previous Puzzle

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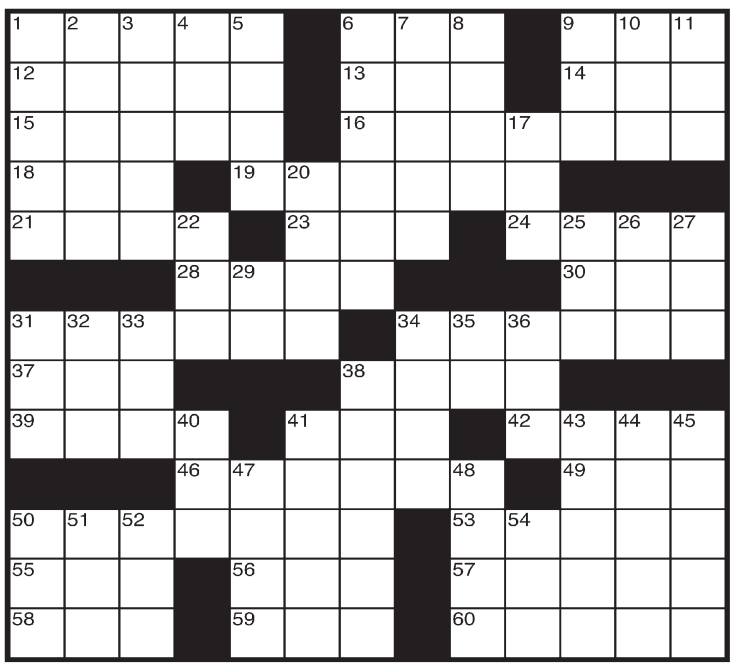

110 Announcements

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THE DEADLINE
for placing a
CLASSIFIED AD
is 4:00 P.M.
TWO BUSINESS DAYS BEFORE PUBLICATION
Publication Days:
Tuesday,Thursday,Saturday

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- **Dollar Tree**
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- **Ryder Bros**
- **VFW**
- **Baker Elk's Lodge**
- **Main Event**
- **Lefty's Tap House**
- **Little Bagel Shop**
- **Baker City Fire Dept.**
- **Haines Sell-Rite**
- **Idle Hour**
- **Salvation Army**

114 Self-Help Group Meetings

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541-805-2229
neo-na.org

AA MEETINGS
Wednesday Nights, 7-8:15pm.
Fort Union Grange Hall, corner of McAlister & Gekeler Lanes.
For more info, call 541-786-1222

AL-ANON Attitude of Gratitude.
Wednesdays, 12:15-1:30pm.
Faith Lutheran Church.
12th & Gekeler, La Grande.
541-786-2051

NARCOTICS ANONYMOUS
Monday, Thursday, & Friday at 8pm. Episcopal Church
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Drug Problem?
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Narcotics Anonymous
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www.neo-na.org

DOES EVERYONE KNOW YOUR BUSINESS
Even if you think they do, you'll have to keep reminding them about it.

T.O.P.S.
Meets every Tuesday Morning
8:30 a.m.-10 a.m.
LDS Church in Island City.
Fragrance Free Group

CELEBRATE RECOVERY
Calvary Baptist Church
Third & Broadway
Baker City, OR
EVERY THURSDAY
6:15 - 8:00 PM

DO YOU HAVE....
HURTS, HABITS and/or HANG UPS?
12 Step Biblical Support
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Thurs., 6:30 - 8:30 PM

114 Self-Help Group Meetings

CELEBRATE RECOVERY
Calvary Baptist Church
Third & Broadway
Baker City, OR
EVERY THURSDAY
6:15 - 8:00 PM

LA GRANDE NOW HAS A GAMBLERS ANONYMOUS MEETING!
Every Friday Night @5pm, 2107 Gekeler Ln, LG, Church of Christ basement. For more info please call 971-219-8411

NARCOTICS ANONYMOUS
Goin' Straight Group
Meetings:
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Start at 8 PM
Episcopal Church Basement
2177 1st Street, Baker City

PEOPLE with PARKINSON'S
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SUPPORT GROUP
Contact Judith at
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Joseph, OR
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Help for persons who have been affected by someone else's drinking
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